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The EPA Administrator, E. Scott Pruitt, signed the following notice on 5/25/2018, and EPA is submitting it for publication in the *Federal Register* (FR). While we have taken steps to ensure the accuracy of this Internet version of the rule, it is not the official version of the rule for purposes of compliance. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's FDSys website (<http://gpo.gov/fdsys/search/home.action>) and on Regulations.gov (<http://www.regulations.gov>) in Docket No. EPA-HQ-OAR-2013-0566. Once the official version of this document is published in the FR, this version will be removed from the Internet and replaced with a link to the official version.

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 50

[EPA-HQ-OAR-2013-0566; FRL-XXX-XX-OAR]

RIN 2060-AT68

Review of the Primary National Ambient Air Quality Standards for Sulfur Oxides

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed action.

SUMMARY: Based on the Environmental Protection Agency's (EPA's) review of the air quality criteria addressing human health effects and the primary national ambient air quality standard (NAAQS) for sulfur oxides (SO_x), the EPA is proposing to retain the current standard, without revision.

DATES: Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

If, by **[INSERT DATE 7 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**, the EPA receives a request from a member of the public to speak at a public hearing concerning the proposed decision (see **SUPPLEMENTARY INFORMATION** below), we will hold a public hearing, with information about the hearing provided in a subsequent notice in the *Federal Register*.

ADDRESSES: You may submit comments, identified by Docket ID No. EPA-HQ-OAR-2013-0566, to the Federal eRulemaking Portal: <http://www.regulations.gov>.

Instructions: Follow the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (i.e., on the web, the cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

If a public hearing is to be held on this proposed action (see **SUPPLEMENTARY INFORMATION** below), in addition to publishing a *Federal Register* notice, the EPA will post information regarding it, including date and time, online at <https://www.epa.gov/so2-pollution/2010-primary-national-ambient-air-quality-standards-naaqs-sulfur-dioxide>.

Docket: All documents in the dockets pertaining to this action are listed on the www.regulations.gov website. This includes documents in the docket for the proposed decision (Docket ID No. EPA-HQ-OAR-2013-0566) and a separate docket, established for the Integrated Science Assessment (ISA) for this review (Docket ID No. EPA-HQ-ORD-2013-0357) that has been incorporated by reference into the docket for this proposed decision. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and may be viewed, with prior arrangement, at the EPA Docket Center.

Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the Air and Radiation Docket Information Center, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744 and the telephone number for the Air and Radiation Docket Information Center is (202) 566-1742.

FOR FURTHER INFORMATION CONTACT: Dr. Nicole Hagan, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Mail Code C504-06, Research Triangle Park, NC 27711; telephone: (919) 541-3153; fax: (919) 541-0237; email: hagan.nicole@epa.gov.

SUPPLEMENTARY INFORMATION:

General Information

Preparing Comments for the EPA

1. Submitting CBI.

Do not submit this information to the EPA through www.regulations.gov or email.

Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to the EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

2. Tips for Preparing Your Comments.

When submitting comments, remember to:

- Identify the action by docket number and other identifying information (subject heading, *Federal Register* date and page number).
- Follow directions – the agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

Public Hearing: If, by **[INSERT DATE 7 DAYS AFTER PUBLICATION IN THE FEDERAL REGISTER]**, the EPA receives a request from a member of the public to speak at a public hearing concerning the proposed decision, we will hold a public hearing, with information about the hearing provided in a subsequent notice in the *Federal Register*. To request a hearing, to register to speak at a hearing or to inquire if a hearing will be held, please contact Ms. Regina Chappell at (919) 541–3650 or by email at chappell.regina@epa.gov. If a public hearing is to be held on this proposed action, the EPA will also post information regarding it, including, date and time, online at <https://www.epa.gov/so2-pollution/2010-primary-national-ambient-air-quality-standards-naaqs-sulfur-dioxide>.

Availability of Information Related to this Action

A number of the documents that are relevant to this proposed decision are available through the EPA's website at <https://www.epa.gov/naaqs/sulfur-dioxide-so2-primary-air-quality-standards>. These documents include the Integrated Review Plan for the Primary National Ambient Air Quality Standard for Sulfur Dioxide (U.S. EPA, 2014a), available at <https://www3.epa.gov/ttn/naaqs/standards/so2/data/20141028so2reviewplan.pdf>, the Integrated Science Assessment for Sulfur Oxides – Health Criteria (U.S. EPA, 2017a), available at <https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=338596>, the Risk and Exposure Assessment for the Review of the National Ambient Air Quality Standard for Sulfur Oxides (U.S. EPA, 2018a), available at <https://www.epa.gov/naaqs/sulfur-dioxide-so2-standards-risk-and-exposure-assessments-current-review> and the Policy Assessment for the Review of the Primary National Ambient Air Quality Standard for Sulfur Oxides (U.S. EPA, 2018b), available at <https://www.epa.gov/naaqs/sulfur-dioxide-so2-standards-policy-assessments-current-review>. These and other related documents are also available for inspection and copying in the EPA docket identified above.

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Executive Summary

This document presents the Administrator's proposed decision in the current review of the primary (health-based) NAAQS for SO_x, a group of closely related gaseous compounds that include sulfur dioxide (SO₂). Of these compounds, SO₂ (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The current primary standard is set at a level of 75 ppb, as the 99th

percentile of daily maximum 1-hour SO₂ concentrations, averaged over 3 years. This document summarizes the background and rationale for the Administrator's proposed decision to retain the current standard, without revision, and solicits comment on this proposed decision and on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision. The EPA solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

This review of the primary SO₂ standard is required by the Clean Air Act (CAA) on a periodic basis. The schedule for completing this review is established by a consent decree, which established May 25, 2018 as the deadline for signature of a notice setting forth the proposed decision in this review and January 28, 2019 as the deadline for signature on a final decision notice.

The last review of the primary SO₂ NAAQS was completed in 2010 (75 FR 35520, June 22, 2010). In that review, the EPA significantly strengthened the primary standard, establishing a 1-hour standard and revoking the 24-hour and annual standards. The 1-hour standard was established to provide protection from respiratory effects associated with exposures as short as a few minutes based on evidence from health studies that documented respiratory effects in people with asthma exposed to SO₂ for 5 to 10 minutes while breathing at elevated rates. Revisions to the NAAQS were accompanied by revisions to the ambient air monitoring and reporting regulations, requiring the reporting of hourly maximum 5-minute SO₂ concentrations, in addition to the hourly concentrations.

Emissions of SO₂ and associated concentrations in ambient air have declined appreciably

since 2010 and over the longer term. For example, emissions nationally are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016 (PA, Figure 2-2; 2014 NEI). Such declines in SO₂ emissions are likely related to the implementation of national control programs developed under the Clean Air Act Amendments of 1990, as well as changes in market conditions, e.g., reduction in energy generation by coal (PA, section 2.1, Figure 2-2; U.S. EIA, 2017). One-hour concentrations of SO₂ in ambient air the U.S. declined more than 82% from 1980 to 2016 at locations continuously monitored over this period (PA, Figure 2-4). The decline since 2000 has been 69% at a larger number of locations continuously monitored since that time (PA, Figure 2-5). Daily maximum 5-minute concentrations have also consistently declined from 2011 to 2016 (PA, Figure 2-6).

In this review, as in past reviews of the primary NAAQS for SO_x, the health effects evidence evaluated in the ISA is focused on SO₂. The health effects of particulate atmospheric transformation products of SO_x, such as sulfates, are addressed in the review of the NAAQS for particulate matter (PM). Additionally, the welfare effects of sulfur oxides and the ecological effects of particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM, while the visibility, climate, and materials damage-related welfare effects of particulate sulfur compounds are being evaluated in the review of the secondary NAAQS for PM.

The proposed decision to retain the current primary NAAQS for SO_x, without revision, has been informed by careful consideration of the key aspects of the currently available health effects evidence and conclusions contained in the ISA, quantitative risk and exposure information presented in the REA, considerations of this evidence and information discussed in the Policy Assessment, advice from the Clean Air Scientific Advisory Committee (CASAC), and

public input received as part of the ongoing review of the primary NAAQS for SO_x.

The health effects evidence newly available in this review, as critically assessed in the ISA in conjunction with the full body of evidence, reaffirms the conclusions from the last review. The health effects evidence continues to support the conclusion that respiratory effects are causally related to short-term SO₂ exposures, including effects related to asthma exacerbation in people with asthma, particularly children with asthma. The clearest evidence for this conclusion comes from controlled human exposure studies, available at the time of the last review, that show that people with asthma experience respiratory effects following very short (e.g., 5-10 minute) exposures to SO₂ while breathing at elevated rates. Epidemiologic evidence, including studies not available in the last review, also supports this conclusion, primarily due to studies reporting positive associations between ambient air concentrations and emergency department visits and hospital admissions, specifically for children.

The quantitative analyses of population exposure and risk also inform the proposed decision. These analyses expand and improve upon the quantitative analyses available in the last review. Unlike the REA available in the last review, which analyzed single-year air quality scenarios for potential standard levels bracketing the now current level, the current REA assesses an air quality scenario for three years of air quality conditions that just meet the now-current standard, considering all of its elements, including its 3-year form. Other ways in which the current REA analyses are improved and expanded include improvements to models, model inputs and underlying databases, including the vastly expanded ambient air monitoring dataset for 5-minute concentrations, available as a result of changes in the last review to data reporting requirements.

Based on this evidence and quantitative information, as well as CASAC advice and

public comment thus far in this review, the Administrator proposes to conclude that the current primary SO₂ standard is requisite to protect public health, with an adequate margin of safety, from effects of SO_x in ambient air and should be retained, without revision. These proposed conclusions are consistent with CASAC recommendations. In its advice to the Administrator, the CASAC concurred with the preliminary conclusions in the draft PA that “the current scientific literature does not support revision of the primary NAAQS for SO₂” (Cox and Diez Roux, 2018b, p. 1 of letter). The CASAC further stated that it “supports retaining the current standard, and specifically recommends that all four elements (indicator, averaging time, form, and level) should remain the same” (Cox and Diez Roux, 2018b, p. 1 of letter). The Administrator solicits comment on the proposed conclusion that the current standard is requisite to protect public health, with an adequate margin of safety, and on the proposed decision to retain the standard, without revision. The Administrator also solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision, as discussed in detail in section II below. The EPA solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

I. Background

This review focuses on the presence in ambient air of SO_x, a group of closely related gaseous compounds that includes SO₂ and sulfur trioxide and of which SO₂ (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The health effects of particulate atmospheric

transformation products of SO_x, such as sulfates, are addressed in the review of the NAAQS for PM (U.S. EPA 2014a, 2016a). Additionally, the ecological welfare effects of sulfur oxides and particulate atmospheric transformation products are being considered in the review of the secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM (U.S. EPA, 2014a, 2017b), while the visibility, climate, and materials damage-related welfare effects of particulate sulfur compounds are being evaluated in the review of the secondary NAAQS for PM.¹

A. Legislative Requirements

Two sections of the Clean Air Act (CAA or the Act) govern the establishment and revision of the NAAQS. Section 108 (42 U.S.C. 7408) directs the Administrator to identify and list certain air pollutants and then to issue air quality criteria for those pollutants. The Administrator is to list those air pollutants that in his “judgment, cause or contribute to air pollution which may reasonably be anticipated to endanger public health or welfare;” “the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;” and “for which . . . [the Administrator] plans to issue air quality criteria. . . .” Air quality criteria are intended to “accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of [a] pollutant in the ambient air” 42 U.S.C. 7408(b). Section 109 (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” NAAQS for pollutants for which air quality criteria are issued. Section 109(b)(1)

¹ Additional information on the review of secondary NAAQS for oxides of nitrogen, oxides of sulfur, and PM with regard to ecological welfare effects is available at: <https://www.epa.gov/naaqs/nitrogen-dioxide-no2-and-sulfur-dioxide-so2-secondary-air-quality-standards> Additional information on the review of the PM NAAQS is available at: <https://www.epa.gov/naaqs/particulate-matter-pm-air-quality-standards>.

defines a primary standard as one “the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, [is] requisite to protect the public health.”² A secondary standard, as defined in section 109(b)(2), must “specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air.”³

The requirement that primary standards provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. It was also intended to provide a reasonable degree of protection against hazards that research has not yet identified. *See Lead Industries Association v. EPA*, 647 F.2d 1130, 1154 (D.C. Cir, 1980); *American Petroleum Institute v. Costle*, 665 F.2d 1176, 1186 (D.C. Cir. 1981); *American Farm Bureau Federation v. EPA*, 559 F.3d 512, 533 (D.C. Cir. 2009); *Association of Battery Recyclers v. EPA*, 604 F. 3d 613, 617-18 (D.C. Cir. 2010). Both kinds of uncertainties are components of the risk associated with pollution

² The legislative history of section 109 indicates that a primary standard is to be set at “the maximum permissible ambient air level . . . which will protect the health of any [sensitive] group of the population,” and that for this purpose “reference should be made to a representative sample of persons comprising the sensitive group rather than to a single person in such a group.” *See* S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 (1970). *See also Lead Industries Association v. EPA*, 647 F.2d 1130, 1152 (D.C. Cir 1980); *American Lung Association v. EPA*, 134 F.3d 388, 389 (D.C. Cir. 1998) (“NAAQS must protect not only average healthy individuals, but also ‘sensitive citizens’—children, for example, or people with asthma, emphysema, or other conditions rendering them particularly vulnerable to air pollution.”).

³ As specified in section 302(h) (42 U.S.C. 7602(h)) effects on welfare include, but are not limited to, “effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility, and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being.”

at levels below those at which human health effects can be said to occur with reasonable scientific certainty. Thus, in selecting primary standards that provide an adequate margin of safety, the Administrator is seeking not only to prevent pollution levels that have been demonstrated to be harmful but also to prevent lower pollutant levels that may pose an unacceptable risk of harm, even if the risk is not precisely identified as to nature or degree. However, the CAA does not require the Administrator to establish a primary NAAQS at a zero-risk level or at background concentrations, *see Lead Industries Association v. EPA*, 647 F.2d at 1156 n.51, but rather at a level that reduces risk sufficiently so as to protect public health with an adequate margin of safety.

In addressing the requirement for an adequate margin of safety, the EPA considers such factors as the nature and severity of the health effects involved, the size of sensitive population(s) at risk,⁴ and the kind and degree of the uncertainties that must be addressed. The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgment. *See Lead Industries Association v. EPA*, 647 F.2d at 1161-62.

In setting primary and secondary standards that are "requisite" to protect public health and welfare, respectively, as provided in section 109(b), the EPA's task is to establish standards that are neither more nor less stringent than necessary for these purposes. In so doing, the EPA may not consider the costs of implementing the standards. *See generally Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 (2001). Likewise, "[a]ttainability and technological feasibility are not relevant considerations in the promulgation of national ambient

⁴ As used here and similarly throughout this notice, the term population (or group) refers to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestage. Section II.B.2 below describes the identification of sensitive groups (called at-risk groups or at-risk populations) in this review.

air quality standards.” *American Petroleum Institute v. Costle*, 665 F.2d at 1185.

Section 109(d)(1) requires that “not later than December 31, 1980, and at 5-year intervals thereafter, the Administrator shall complete a thorough review of the criteria published under section 108 and the national ambient air quality standards . . . and shall make such revisions in such criteria and standards and promulgate such new standards as may be appropriate. . . .”

Section 109(d)(2) requires that an independent scientific review committee “shall complete a review of the criteria . . . and the national primary and secondary ambient air quality standards. . . and shall recommend to the Administrator any new . . . standards and revisions of existing criteria and standards as may be appropriate” Since the early 1980s, this independent review function has been performed by the Clean Air Scientific Advisory Committee (CASAC).⁵

B. Related SO₂ Control Programs

States are primarily responsible for ensuring attainment and maintenance of ambient air quality standards once the EPA has established them. Under section 110 of the Act, 42 U.S.C. 7410, and related provisions, states are to submit, for EPA approval, state implementation plans (SIPs) that provide for the attainment and maintenance of such standards through control programs directed to sources of the pollutants involved. The states, in conjunction with the EPA, also administer the prevention of significant deterioration program that covers these pollutants. *See* 42 U.S.C. 7470–7479. In addition, federal programs provide for nationwide reductions in emissions of these and other air pollutants under Title II of the Act, 42 U.S.C. 7521–7574, which involves controls for automobile, truck, bus, motorcycle, nonroad engine and equipment, and

⁵ Lists of CASAC members and members of the CASAC Sulfur Oxides Review Panel are available at:

<https://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Sulfur%20Oxides%20Panel>.

aircraft emissions; the new source performance standards under section 111 of the Act, 42 U.S.C. 7411; and the national emission standards for hazardous air pollutants under section 112 of the Act, 42 U.S.C. 7412.

C. Review of the Air Quality Criteria and Standard for Sulfur Oxides

The initial air quality criteria for SO_x were issued in 1969 (34 FR 1988, February 11, 1969). Based on these criteria, the EPA, in initially promulgating NAAQS for SO_x in 1971, established the indicator as SO₂. The SO_x are a group of closely related gaseous compounds that include sulfur dioxide and sulfur trioxide and of which sulfur dioxide (the indicator for the current standard) is the most prevalent in the atmosphere and the one for which there is a large body of scientific evidence on health effects. The two primary standards set in 1971 were 0.14 parts per million (ppm) averaged over a 24-hour period, not to be exceeded more than once per year, and 0.03 ppm, as an annual arithmetic mean (36 FR 8186, April 30, 1971).

The first review of the air quality criteria and primary standards for SO_x was initiated in the early 1980s and concluded in 1996 with the decision to retain the standards without revision (61 FR 25566, May 22, 1996). In reaching this decision, the Administrator considered the evidence newly available since the standards were set that documented asthma-related respiratory effects in people with asthma exposed for very short periods, such as 5 to 10 minutes. Based on his consideration of an exposure analysis using the then-limited monitoring data and early exposure modeling methods, the Administrator judged that revisions to the standards were not needed to provide requisite public health protection from SO_x in ambient air at that time (61 FR 25566, May 22, 1996). This decision was challenged and the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit) found that the EPA had failed to adequately explain its determination that no revision to the primary SO₂ standards was appropriate and remanded the

determination back to the EPA for further explanation (*American Lung Association v. EPA*, 134 F.3d 388 [D.C. Cir. 1998]).

This remand was addressed in the most recent review, which was completed in 2010. In that review, the EPA promulgated a new 1-hour standard and also promulgated provisions for the revocation of the then-existing 24-hour and annual primary standards.⁶ The new 1-hour standard was set with a level of 75 parts per billion (ppb), a form of the 3-year average of the annual 99th percentile of daily maximum 1-hour SO₂ concentrations, and with SO₂ as the indicator. The Administrator judged that such a standard would provide the requisite protection for at-risk populations, such as people with asthma, against the array of adverse respiratory health effects related to short-term SO₂ exposures, including those as short as 5 minutes. With regard to longer-term exposures, the new standard was expected to maintain 24-hour and annual concentrations generally well below the levels of the previous standards, and the available evidence did not indicate the need for separate standards designed to protect against longer-term exposures (75 FR 35520, June 22, 2010). The EPA also revised the SO₂ ambient air monitoring regulations to require that monitoring agencies using continuous SO₂ methods report the highest 5-minute concentration for each hour of the day;⁷ agencies may report all twelve 5-minute concentrations for each hour, including the maximum, although it is not required (75 FR 35568, June 22, 2010). This rule was challenged in court, and the D.C. Circuit denied or dismissed on jurisdictional

⁶ Timing and related requirements for the implementation of the revocation are specified in 40 CFR 50.4(e).

⁷ The rationale for this requirement was described as providing additional monitoring data for use in subsequent reviews of the primary standard, particularly for use in considering the extent of protection provided by the 1-hour standard against 5-minute peak SO₂ concentrations of concern (75 FR 35568, June 22, 2010). In establishing this requirement, the EPA described such data as being “of high value to inform future health studies and, subsequently, future SO₂ NAAQS reviews” (75 FR 35568, June 22, 2010).

grounds all the claims in the petitions for review. *National Environmental Development Association's Clean Air Project v. EPA*, 686 F.3d 803, 805 (D.C. Cir. 2012).

In May 2013, the EPA initiated the current review by issuing a call for information in the *Federal Register* and also announcing a public workshop to inform the review (78 FR 27387, May 10, 2013). As was the case for the prior review, this review is focused on health effects associated with SO_x and the public health protection afforded by the existing standard. Participants in the kickoff workshop included a wide range of external experts as well as EPA staff representing a variety of areas of expertise (e.g., epidemiology, human and animal toxicology, statistics, risk/exposure analysis, atmospheric science, and biology). Workshop discussions focused on key policy-relevant issues around which the Agency would structure the review and the newly available scientific information related to these issues. Based in part on the workshop discussions, the EPA developed the draft integrated review plan (IRP) outlining the schedule, process, and key policy-relevant questions to guide this review of the SO_x air quality criteria and standards (U.S. EPA, 2014b). The draft IRP was released for public comment and was reviewed by the CASAC at a public teleconference on April 22, 2014 (79 FR 14035, March 12, 2014; Frey and Diez Roux, 2014). The final IRP was developed with consideration of comments from the CASAC and the public (U.S. EPA, 2014a; 79 FR 16325, March 25, 2014; 79 FR 66721, November 10, 2014).

As an early step in development of the Integrated Science Assessment (ISA) for this review, the EPA's National Center for Environmental Assessment (NCEA) hosted a public workshop at which preliminary drafts of key ISA chapters were reviewed by subject matter experts (79 FR 33750, June 12, 2014). Comments received from this review as well as comments from the public and the CASAC on the draft IRP were considered in preparation of the first draft

ISA (U.S. EPA, 2015), released in November 2015 (80 FR 73183, November 24, 2015). The first draft ISA was reviewed by the CASAC at a public meeting in January 2016 and a public teleconference in April 2016 (80 FR 79330, December 21, 2015; 80 FR 79330, December 21, 2015; Diez Roux, 2016). The EPA released the second draft ISA in December 2016 (U.S. EPA, 2016b; 81 FR 89097, December 9, 2016), which was reviewed by the CASAC at a public meeting in March 2017 and a public teleconference in June 2017 (82 FR 11449, February 23, 2017; 82 FR 23563, May 23, 2017; Diez Roux, 2017a). The final ISA was released in December 2017 (U.S. EPA, 2017a; 82 FR 58600, December 13, 2017).

In considering the need for quantitative exposure and risk analyses in this review, the EPA completed the Risk and Exposure Assessment (REA) Planning Document in February 2017 (U.S. EPA, 2017c; 82 FR 11356, February 22, 2017), and held a consultation with the CASAC at a public meeting in March 2017 (82 FR 11449, February 23, 2017; Diez Roux, 2017b). In consideration of the CASAC's comments at that consultation and public comments, the EPA developed the draft REA and draft Policy Assessment (PA), which were released on August 24, 2017 (U.S. EPA, 2017d,e; 82 FR 43756, September 19, 2017). The draft REA and draft PA were reviewed by the CASAC on September 18-19, 2017 (82 FR 37213, August 9, 2017; Cox and Diez Roux, 2018a,b). The EPA considered the advice and comments from the CASAC on the draft REA and draft PA as well as public comments, in developing the final REA and final PA, which were released in early May 2018 (U.S. EPA, 2018a,b).

The schedule for completion of this review is governed by a consent decree resolving a lawsuit filed in July 2016 by a group of plaintiffs which included a claim that the EPA had failed

to complete its review of the primary SO₂ NAAQS within five years, as required by the CAA.⁸

The consent decree, which was entered by the court on April 28, 2017, provides that the EPA will sign, for publication, notices setting forth proposed and final decisions concerning its review of the primary NAAQS for SO_x no later than May 25, 2018 and January 28, 2019, respectively.⁹

D. Air Quality Information

This section presents information on sources and emissions of SO₂ and ambient concentrations, with a focus on information that is most relevant for the review of the primary SO₂ standard. This section is drawn from the more detailed discussion of SO₂ air quality in the PA and the ISA. It presents a summary of SO₂ sources and emissions (II.B.1) and ambient concentrations (II.B.2).

1. Sources and Emissions of Sulfur Oxides

Sulfur oxides are emitted into air from specific sources (e.g., fuel combustion processes) and are also formed in the atmosphere from other atmospheric compounds (e.g., as an oxidation product of reduced sulfur compounds, such as sulfides). Sulfur oxides are also transformed in the atmosphere to particulate sulfur compounds, such as sulfates.¹⁰ Sulfur oxides known to occur in

⁸ See Complaint, *Center for Biological Diversity et al. v. McCarthy*, No. 3:16-cv-03796-VC, (N.D. Cal., filed July 7, 2016), Doc. No. 1.

⁹ Consent Judgment at 4, *Center for Biological Diversity et al. v. McCarthy*, No. 3:16-cv-03796-VC (N.D. Cal., entered April 28, 2017), Doc. No. 37.

¹⁰ Some sulfur compounds formed from or emitted with SO_x are very short-lived (ISA, pp. 2-23 to 2-24). For example, studies in the 1970s and 1980s identified particle-phase sulfur compounds, including inorganic SO₃⁻² complexed with Fe(III) in the particles emitted by a smelter near Salt Lake City, UT. Subsequent studies reported rapid oxidation of such compounds, “on the order of seconds to minutes” and “further accelerated by low pH” (ISA, p. 2-24). Thus, “[t]he highly acidic aqueous conditions that arise once smelter plume particles equilibrate with the ambient atmosphere ensure that S(IV)-Fe(III) complexes have a small probability of persisting and becoming a matter of concern for human exposure” (ISA, 2-24).

the troposphere include SO₂ and sulfur trioxide (SO₃) (ISA, section 2.3). With regard to SO₃, it “is known to be present in the emissions of coal-fired power plants, factories, and refineries, but it reacts with water vapor in the stacks or immediately after release into the atmosphere to form H₂SO₄” and “gas-phase H₂SO₄. . . . quickly condenses onto existing atmospheric particles or participates in new particle formation” (ISA, section 2.3). Thus, as a result of rapid atmospheric chemical reactions involving SO₃, the most prevalent sulfur oxide in the atmosphere is SO₂ (ISA, section 2.3).¹¹

Fossil fuel combustion is the main anthropogenic source of SO₂ emissions, while volcanoes and landscape fires (wildfires as well as controlled burns) are the main natural sources (ISA, section 2.1).¹² Industrial chemical production, pulp and paper production, natural biological activity (plants, fungi, and prokaryotes), and volcanoes are among many sources of reduced sulfur compounds that contribute, through various oxidation reactions in the atmosphere, to the formation of SO₂ in the atmosphere (ISA, section 2.1). Anthropogenic SO₂ emissions originate primarily from point sources, including coal-fired electricity generating units (EGUs) and other industrial facilities (ISA, section 2.2.1). The largest SO₂-emitting sector within the U.S. is electricity generation, and 97% of SO₂ from electricity generation is from coal combustion. Other anthropogenic sources of SO₂ emissions include industrial fuel combustion and process emissions, industrial processing, commercial marine activity, and the use of fire in

¹¹ The health effects of particulate atmospheric transformation products of SO_x, such as sulfates, are addressed in the review of the NAAQS for PM (U.S. EPA 2014a, 2016a).

¹² A modeling analysis estimated annual mean SO₂ concentrations for 2001 in the absence of any U.S. anthropogenic emissions of SO₂ (2008 ISA, section 2.5.3; ISA, section 2.5.5). Such concentrations are referred to as U.S. background or USB. The 2008 ISA analysis estimated USB concentrations of SO₂ to be below 0.01 ppb over much of the U.S., ranging up to a maximum of 0.03 ppb (ISA, section 2.5.5).

landscape management and agriculture (ISA, section 2.2.1).

National average SO₂ emissions are estimated to have declined by 82% over the period from 2000 to 2016, with a 64% decline from 2010 to 2016 (PA, Figure 2-2; 2014 NEI). Such declines in SO₂ emissions are likely related to the implementation of national control programs developed under the Clean Air Act Amendments of 1990, including Phase I and II of the Acid Rain Program, the Clean Air Interstate Rule, the Cross-State Air Pollution Rule, and the Mercury Air Toxic Standards,¹³ as well as changes in market conditions, e.g., reduction in energy generation by coal (PA, section 2.1, Figure 2-2; U.S. EIA, 2017).¹⁴ Regulations on sulfur content of diesel fuel, both fuel for onroad vehicles and nonroad engines and equipment, may also contribute to declining trends in SO₂ emissions.¹⁵ Declines in emissions from all sources between 1971, when SO_x NAAQS were first established, and 1990, when the Amendments were adopted, were on the order of 5,000 tpy deriving primarily from reductions in emissions from the metals processing sector (ISA, Figure 2-5).

2. Ambient Concentrations

Ambient air concentrations of SO₂ in the U.S. have declined substantially from 1980 to 2016, more than 82% in terms of the form of the current standard (the 99th percentile daily maximum 1-hour concentrations averaged over three years) at locations continuously monitored

¹³ When established, the MATS Rules was estimated to reduce SO₂ emissions from power plants by 41% beyond the reductions expected from the Cross State Air Pollution Rule (U.S. EPA, 2011).

¹⁴ In 2014, the EPA promulgated Tier 3 Motor Vehicle Emission and Fuel Standards that set emissions standards for new vehicles and lowered the sulfur content of gasoline. Reductions in SO₂ emissions resulting from these standards are expected to be more than 14,000 tons in 2018 (U.S. EPA, 2014c).

¹⁵ See <https://www.epa.gov/diesel-fuel-standards/diesel-fuel-standards-and-rulemakings#nonroad-diesel>

over this period (PA, Figure 2-4).¹⁶ The decline since 2000 has been 69% at the larger number of locations continuously monitored since that time (PA, Figure 2-5).¹⁷

As a result of the reporting requirements promulgated in 2010 (as summarized in section I.C above) maximum hourly five-minute concentrations of SO₂ in ambient air are available at SO₂ NAAQS compliance monitoring sites (PA, Figure 2-3; FR 75 35554, June 22, 2010).¹⁸ These newly available data document reductions in peak 5-minute concentrations across the U.S. For example, over the period from 2011 to 2016, the 99th percentile 5-minute SO₂ concentrations declined approximately 53% (PA, Figure 2-6, Appendix B).

Concentrations of SO₂ vary across the U.S. and tend to be higher in areas with sources having relatively higher SO₂ emissions (e.g., locations influenced by emissions from EGUs). Consistent with the locations of larger SO₂ sources, higher concentrations are primarily located in the eastern half of the continental U.S., especially in the Ohio River valley, upper Midwest, and along the Atlantic coast (PA, Figure 2-7). The point source nature of SO₂ emissions contributes to the relatively high spatial variability of SO₂ concentrations compared with pollutants such as ozone (ISA, section 3.2.3). Another factor in the spatial variability is the dispersion and oxidation of SO₂ in the atmosphere, processes that contribute to decreasing concentrations with increasing distance from the source. Point source emissions of sulfur oxides

¹⁶ This decline is the average of observations at 24 monitoring sites that have been continuously operating from 1980-2016.

¹⁷ This decline is the average of observations at 193 monitoring sites that have been continuously operating across 2000-2016.

¹⁸ Such measurements were available for fewer than 10% of monitoring sites at the time of the last review. Of the monitors reporting 5-minute data in 2016, almost 40% are reporting all twelve 5-minute SO₂ measurements in each hour while about 60% are reporting the maximum 5-minute SO₂ concentration in each hour (PA, section 2.2). The expanded dataset has provided a more robust foundation for the quantitative analyses in the REA for this review.

create a plume of higher concentrations, which may or may not impact large portions of surrounding populated areas depending on meteorological conditions and terrain.

Analyses in the ISA of data for 2013-2015 in six areas indicate that 1-hour daily maximum SO₂ concentrations vary across seasons, with the greatest variations seen in the upper percentile concentrations (versus average or lower percentiles) for each season (ISA, section 2.5.3.2).¹⁹ This seasonal variation as well as month-to-month variations are generally consistent with month-to-month emissions patterns and the expected atmospheric chemistry of SO₂ for a given season. Consistent with the nationwide diel patterns reported in the last review, 1-hour average and 5-minute hourly maximum SO₂ concentrations for 2013-2015 in all six areas evaluated were generally low during nighttime and approached maxima values during daytime hours (ISA, section 2.5.3.3, Figures 2-23 and 2-24). The timing and duration of daytime maxima in the six sites evaluated in the ISA were likely related to a combination of source emissions and meteorological parameters (ISA, section 2.5.3.3; U.S. EPA 2008a, section 2.5.1).

II. Rationale for Proposed Decision

This section presents the rationale for the Administrator's proposed decision to retain the current primary SO₂ standard. This rationale is based on a thorough review of the latest scientific

¹⁹ The six "focus areas" evaluated in the ISA are: Cleveland, OH; Pittsburgh, PA; New York City, NY; St. Louis, MO-IL; Houston, TX; and Gila County, AZ (ISA, section 2.5.2.2). These six locations were selected based on (1) their relevance to current health studies (i.e., areas with peer-reviewed, epidemiologic analysis); (2) the existence of four or more monitoring sites located within the area boundaries; and (3) the presence of several diverse SO₂ sources within a given focus area boundary.

information generally published through August 2016,²⁰ as presented in the ISA, on human health effects associated with SO₂ and pertaining to the presence of SO_x in ambient air. The Administrator's rationale also takes into account: (1) the PA evaluation of the policy-relevant information in the ISA and quantitative analyses of air quality, human exposure and health risks in the REA; (2) CASAC advice and recommendations, as reflected in discussions of drafts of the ISA, REA, and PA at public meetings and in the CASAC's letters to the Administrator; and (3) public comments received during the development of these documents.

In presenting the rationale for the Administrator's proposed decision and its foundations, section II.A provides background on the general approach for review of the primary SO₂ standard, including a summary of the approach used in the last review (section II.A.1) and the general approach for the current review (section II.A.2). Section II.B summarizes the currently available health effects evidence, focusing on consideration of key policy-relevant aspects. Section II.C summarizes the exposure and risk information for this review, drawing on the quantitative analyses for SO₂, presented in the REA. Section II.D presents the Administrator's proposed conclusions on the current standard (section II.D.3), drawing on both evidence-based and exposure/risk-based considerations (section II.D.1) and advice from the CASAC (section II.D.2).

A. General Approach

The past and current approaches described below are both based, most fundamentally, on

²⁰ In addition to the review's opening "call for information" (78 FR 27387, May 10, 2013), "the U.S. EPA routinely conducted literature searches to identify relevant peer-reviewed studies published since the previous ISA (i.e., from January 2008 through August 2016)" (ISA, p. 1-3). References that are cited in the ISA, the references that were considered for inclusion but not cited, and electronic links to bibliographic information and abstracts can be found at: <https://hero.epa.gov/hero/sulfur-oxides>.

using the EPA's assessments of the current scientific evidence and associated quantitative analyses to inform the Administrator's judgment regarding a primary standard for SO_x that protects public health with an adequate margin of safety. The EPA's assessments are primarily documented in the ISA, REA and PA, all of which have received CASAC review and public comment (80 FR 73183, November 24, 2015; 81 FR 89097, December 9, 2016; 82 FR 11356, February 22, 2017; 82 FR 43756, September 19, 2017). In bridging the gap between the scientific assessments of the ISA and REA and the judgments required of the Administrator in determining whether the current standard remains requisite to protect public health with an adequate margin of safety, the PA evaluates policy implications of the evaluation of the current evidence in ISA and the quantitative analyses in the REA. In evaluating the health protection afforded by the current standard, the four basic elements of the NAAQS (indicator, averaging time, level, and form) are considered collectively.

We note that in drawing conclusions with regard to the primary standard, the final decision on the adequacy of the current standard is largely a public health policy judgment to be made by the Administrator. The Administrator's final decision will draw upon scientific information and analyses about health effects, population exposure and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the scientific evidence and analyses. This approach is based on the recognition that the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. This approach is consistent with the requirements of the NAAQS provisions of the Clean Air Act and with how the EPA and the courts have historically interpreted the Act. These provisions require the

Administrator to establish primary standards that, in the judgment of the Administrator, are requisite to protect public health with an adequate margin of safety. In so doing, the Administrator seeks to establish standards that are neither more or less stringent than necessary for this purpose. The Act does not require that primary standards be set at a zero-risk level, but rather at a level that avoids unacceptable risks to public health, including the health of sensitive groups.²¹

1. Approach in the Last Review

The last review of the primary NAAQS for SO_x was completed in 2010 (75 FR 35520, June 22, 2010). The decision in that review to substantially revise the standards (establishing a 1-hour standard and revoking the 24-hour and annual standards) was based on the extensive body of evidence of respiratory effects in people with asthma that has expanded in this area over the four decades since the first SO₂ standards were set in 1971 (U.S. EPA 1982, 1986, 1994, 2008a). In so doing, the 2010 decision considered the full body of evidence, as assessed in the 2008 ISA; the 2009 REA, which included the staff assessment of the policy-relevant information contained in the ISA and analyses of air quality, exposure and risk; the advice and recommendations of the CASAC; and public comment. In addition to epidemiologic evidence linking respiratory outcomes in people with asthma to short-term SO₂ air quality metrics, a key element of the expanded evidence base in the 2010 review was a series of controlled human exposure studies which document bronchoconstriction-related effects on lung function in people with asthma

²¹ As noted in section I.A above, such protection is specified for the sensitive group of individuals and not to a single person in the sensitive group (see S. Rep. No. 91-1196, 91st Cong., 2d Sess. 10 [1970]).

exposed while breathing at elevated rates²² for periods as short as five minutes. Another key element was the air quality database, expanded since the previous review (completed in 1996), which documented the then-recent pattern of peak 5-minute SO₂ concentrations. The EPA used these data in the quantitative exposure and risk assessments to provide an up-to-date ambient air quality context for interpreting the health effects evidence in the 2010 review. Together these aspects of the 2010 review additionally addressed the issues raised in the court remand to the EPA of the Agency's 1996 decision not to revise the standards at that time to specifically address 5-minute exposures (75 FR 35523, June 22, 2010). In so doing, the EPA strengthened the primary NAAQS for SO_x to provide the requisite protection of public health with an adequate margin of safety and to specifically afford increased protection for at-risk populations, such as people with asthma, against adverse respiratory health effects related to short-term SO₂ exposures (75 FR 35550, June 22, 2010).

Thus, the 2010 decision focused on the effects most pertinent to SO_x in ambient air and recognized the long-standing evidence regarding the sensitivity of some people with asthma to brief SO₂ exposures experienced while breathing at elevated rates. The Administrator gave particular attention to the robust evidence base, comprised of findings from controlled human exposure, epidemiologic, and animal toxicological studies that collectively were judged “sufficient to infer a causal relationship” between short-term SO₂ exposures ranging from 5

²² The phrase “elevated ventilation” (or “moderate or greater exertion”) was used in the 2009 REA and *Federal Register* notices in the last review to refer to activity levels that in adults would be associated with ventilation rates at or above 40 liters per minute; an equivalent ventilation rate was derived in order to identify corresponding rates for the range of ages and sizes of the simulated populations (U.S. EPA, 2009, section 4.1.4.4). Accordingly, these phrases are used in the current review when referring to REA analyses from the last review. Otherwise, however, the documents for this review generally use the phrase “elevated breathing rates” to refer to the same situation.

minutes to 24 hours and respiratory morbidity (75 FR 35535, June 22, 2010). The “definitive evidence” for this conclusion came from studies of 5- to 10-minute controlled exposures that reported respiratory symptoms and decreased lung function in exercising individuals with asthma (2008 ISA, section 5.3). Supporting evidence was provided by epidemiologic studies of a broader range of respiratory outcomes, with uncertainty noted about the magnitude of the study effect estimates, quantification of the exposure concentration-response relationship, potential confounding by copollutants, and other areas (75 FR 35535-36, June 22, 2010; 2008 ISA, section 5.3).

The conclusions reached in the last review were based primarily on interpretation of the short-term health effects evidence, particularly the interpretation of the evidence from controlled human exposure studies within the context of the quantitative exposure and risk analyses. The epidemiologic evidence also provided support for various aspects of the decision. In making judgments on the public health significance of health effects related to ambient air-related SO₂ exposures, the Administrator considered statements from the American Thoracic Society (ATS) regarding adverse effects of air pollution,²³ the CASAC’s written advice and recommendations,²⁴ and judgments made by the EPA in considering similar effects in previous NAAQS reviews (75 FR 35526 and 35536, June 22, 2010; ATS, 1985, 2000). Based on these considerations, the

²³ The 1999 statement of the ATS (published in 2000) on “What Constitutes an Adverse Health Effect of Air Pollution?” is “intended to provide guidance to policy makers and others who interpret the scientific evidence on the health effects of air pollution for the purpose of risk management” and describes “principles to be used in weighing the evidence” when considering what may be adverse and nonadverse effects on health (ATS, 2000).

²⁴ For example, the CASAC letter on the first draft SO₂ REA to the Administrator stated: “CASAC believes strongly that the weight of clinical and epidemiology evidence indicates there are detectable clinically relevant health effects in sensitive subpopulations down to a level at least as low as 0.2 ppm SO₂” (Henderson, 2008).

Administrator, in reaching decisions in the last review, gave weight to the findings of respiratory effects in exercising people with asthma after 5- to 10-minute exposures as low as 200 ppb. With regard to higher exposures, at or above 400 ppb, she noted their association with respiratory symptoms as indication of their clear adversity, as well as the greater number of study subjects responding with lung function decrements. Moreover, she took note of the greater severity of the response, recognizing effects associated with exposures as low as 200 ppb to be less severe (75 FR 35547, June 22, 2010).

In reaching her conclusion on the adequacy of the then-existing primary standards, the Administrator gave particular attention to the exposure and risk estimates from the 2009 REA for air quality conditions just meeting the then-existing (24-hour and annual) standards. In so doing, the Administrator also noted epidemiologic study findings of associations with respiratory outcomes in studies of locations where maximum 24-hour average SO₂ concentrations were below the level of the then existing 24-hour standard. The 2009 REA estimated that substantial percentages of children with asthma might be expected to experience at least once annually, exposures that had been associated with moderate or greater lung function decrements²⁵ in the controlled human exposure studies (75 FR 35536, June 22, 2010). The Administrator judged that

²⁵ In assessments for NAAQS reviews, the magnitude of lung function responses described as indicative of a moderate response include increases in specific airway resistance (sRaw) of at least 100% (e.g., 2008 ISA; U.S. EPA, 1994, Table 8; U.S. EPA, 1996, Table 8-3). The moderate category has also generally included reductions in forced expiratory volume in 1 second (FEV₁) of 10 to 20% (e.g., U.S. EPA, 1996, Table 8). For the 2008 ISA, the midpoint of that range (15%) was used to indicate a moderate response. A focus on 15% reduction in FEV₁ was also consistent with the relationship observed between sRaw and FEV₁ responses in the Linn et al. studies (1987, 1990) for which “a 100% increase in sRaw roughly corresponds to a 12 to 15% decrease in FEV₁” (U.S. EPA, 1994, p. 20). Thus, in the 2008 review, moderate or greater SO₂-related bronchoconstriction or decrements in lung function referred to the occurrence of at least a doubling in sRaw or at least a 15% reduction in FEV₁ (2008 ISA, p. 3-5).

such exposures can result in adverse health effects in people with asthma and found that the estimated population frequencies for such exposures (24% of at-risk population with at least one occurrence per year at or above 400 ppb and 73% with at least one occurrence per year at or above 200 ppb) were significant from a public health perspective and that the then-existing primary standards did not adequately protect public health (75 FR 35536, June 22, 2010).

Based on consideration of the entire body of evidence and information available in the review, as well as the advice from the CASAC and public comments, the Administrator concluded that the appropriate approach to revising the standards was to replace the then-existing 24-hour standard with a new, short-term standard set to provide requisite protection with an adequate margin of safety to people with asthma and afford protection from the adverse health effects of 5-minute to 24-hour SO₂ exposures (75 FR 35536, June 22, 2010). Accordingly, the available information was then considered in reaching conclusions on the four elements of such a new standard: indicator, averaging time, form, and level. Further, upon reviewing the evidence with regard to the potential for effects from long-term exposures, the Administrator revoked the annual standard. In so doing, she recognized the lack of sufficient health evidence to support a long-term standard and that the new short-term standard would have the effect of generally maintaining the annual SO₂ concentrations well below the level of the revoked annual standard (75 FR 35550, June 22, 2010).

With regard to the indicator for the new short-term standard, the EPA continued to focus on SO₂ as the most appropriate indicator for SO_x because the available scientific information regarding health effects was overwhelmingly indexed by SO₂. Furthermore, although the presence of SO_x species other than SO₂ in ambient air had been recognized, no alternative to SO₂ had been advanced as a more appropriate surrogate for SO_x (75 FR 35536, June 22, 2010).

Controlled human exposure studies and animal toxicological studies provided specific evidence for health effects following exposures to SO₂, and epidemiologic studies typically analyzed associations of health outcomes with concentrations of SO₂. Based on the information available in the last review and consistent with the views of the CASAC that “for indicator, SO₂ is clearly the preferred choice” (Samet, 2009, p. 14), the Administrator concluded it was appropriate to continue to use SO₂ as the indicator for a standard that was intended to address effects associated with exposure to SO₂, alone or in combination with other SO_x (75 FR 35536, June 22, 2010). In so doing, the EPA recognized that measures leading to reductions in population exposures to SO₂ will also likely reduce exposures to other SO_x (75 FR 35536, June 22, 2010).

With regard to the averaging time for the new standard, the Administrator judged that the requisite protection from 5- to 10-minute exposure events could be provided without having a standard with a 5-minute averaging time (75 FR 35539, June 22, 2010). She further judged that a standard with a 5-minute averaging time would result in significant and unnecessary instability in public health protection (75 FR 35539, June 22, 2010).²⁶ Accordingly, she considered longer averaging times.

Results of air quality analyses in the REA suggested that a standard based on 24-hour average SO₂ concentrations would not likely be an effective or efficient approach for addressing 5-minute peak SO₂ concentrations, likely over-controlling in some areas while under-controlling in others (2009 REA, section 10.5.2.2). In contrast, these same analyses suggested that a 1-hour averaging time would be more efficient and would be effective at limiting 5-minute peaks of SO₂ (2009 REA, section 10.5.2.2.). Drawing on this information, the Administrator concluded that a

²⁶ Such instability could reduce public health protection by disrupting an area’s ongoing implementation plans and associated control programs (75 FR 35537, June 22, 2010).

1-hour standard, with the appropriate form and level, would be likely to substantially reduce 5- to 10-minute peaks of SO₂ that had been shown in controlled human exposure studies to result in increased prevalence of respiratory symptoms and/or decrements in lung function in exercising people with asthma (75 FR 35539, June 22, 2010). Further, she found that a 1-hour standard could substantially reduce the upper end of the distribution of SO₂ concentrations in ambient air that were more likely to be associated with respiratory outcomes (75 FR 35539, June 22, 2010).

The Administrator additionally took note of advice from the CASAC. The CASAC stated that the REA had presented a “convincing rationale” for a 1-hour standard and that “a one-hour standard is the preferred averaging time” (Samet, 2009, pp. 15, 16). The CASAC further stated that it was “in agreement with having a short-term standard” and found that “the REA supports a one-hour standard as protective of public health” (Samet, 2009, p. 1). Thus, in consideration of the available information summarized here and the CASAC’s advice, the Administrator concluded that a 1-hour standard (given the appropriate level and form) was an appropriate means of controlling short-term exposures to SO₂ ranging from 5 minutes to 24 hours (75 FR 35539, June 22, 2010).

With regard to the statistical form for the new 1-hour standard, the Administrator judged that the form of the standard should reflect the health effects evidence presented in the ISA that indicated that the percentage of people with asthma affected and the severity of the response increased with increasing SO₂ concentrations (75 FR 35541, June 22, 2010). She additionally found it reasonable to consider stability (e.g., to avoid disruption of programs implementing the standard and the related public health protections from those programs) as part of her consideration of the form for the standard (75 FR 35541, June 22, 2010). In so doing, she noted that a concentration-based form averaged over three years would likely be appreciably more

stable than a no-exceedance based form, which had been the form of the then-existing 24-hour standard (75 FR 35541, June 22, 2010). The CASAC additionally stated that “[t]here is adequate information to justify the use of a concentration-based form averaged over 3 years” (Samet, 2009, p. 16). In consideration of this information, the Administrator judged a concentration-based form averaged over three years to be most appropriate (75 FR 35541, June 22, 2010).

In selecting a specific concentration-based form, the Administrator considered health evidence from the ISA as well as air quality, exposure, and risk information from the REA. In so doing, the Administrator concluded that the form of a new 1-hour standard should be especially focused on limiting the upper end of the distribution of ambient SO₂ concentrations (i.e., above 90th percentile SO₂ concentrations) in order to provide protection with an adequate margin of safety against effects observed in controlled human exposure studies and associated with ambient air SO₂ concentrations in epidemiologic studies (75 FR 35541, June 22, 2010). The Administrator further noted that, based on results of air quality and exposure analyses in the REA, a 99th percentile form was likely to be appreciably more effective at achieving the desired control of 5-minute peak exposures than a 98th percentile form (75 FR 35541, June 22, 2010). Thus, the Administrator selected a 99th percentile form averaged over three years (75 FR 35541, June 22, 2010).

Lastly, based on the body of scientific evidence and information available, as well as CASAC recommendations and public comment, the Administrator decided on a standard level that, in combination with the specified choice of indicator, averaging time and form, would be requisite to protect public health, including the health of at-risk populations, with an adequate margin of safety. In reaching the decision on a level for the new 1-hour standard, the Administrator gave primary emphasis to the body of health effects evidence assessed in the ISA.

In so doing, she noted that the controlled human exposure studies provided the most direct evidence of respiratory effects from exposure to SO₂ (75 FR 35546, June 22, 2010). The Administrator drew on evidence from these studies in reaching judgments on the magnitude of adverse respiratory effects and associated potential public health significance for the air quality exposure and risk analysis results of air quality scenarios for conditions just meeting alternative levels for a new 1-hour standard (described in the 2009 REA).

In light of judgments regarding the health effects evidence, the Administrator considered what the findings of the 2009 REA exposure analyses indicated with regard to varying degrees of protection that different 1-hour standard levels might be expected to provide against 5-minute exposures to concentrations of 200 ppb and 400 ppb, given the specified choice of indicator, averaging time, and form.²⁷ For example, the single-year exposure assessment for St. Louis²⁸ estimated that a 1-hour standard at 100 ppb would likely protect more than 99% of children with asthma in that city from experiencing any days in a year with at least one 5-minute exposure at or above 400 ppb while at moderate or greater exertion, and approximately 97% of those children with asthma from experiencing any days in a year with at least one exposure at or above 200 ppb

²⁷ The Administrator additionally noted the results of the analysis of the limited available air quality data for 5-minute SO₂ concentrations with regard to prevalence of higher 5-minute concentrations at monitor sites when data were adjusted to just meet a standard level of 100 ppb. This 40-county analysis indicated for a 1-hour standard level of 100 ppb a maximum annual average of two days per year with 5-minute concentrations above 400 ppb and 13 days with 5-minute concentrations above 200 ppb (75 FR 35546, June 22, 2010).

²⁸ With regard to the results for the two study areas assessed in the 2009 REA, the EPA considered the St. Louis results to be more informative to consideration of the adequacy of protection associated with the then-current and alternative standards (75 FR 35528, June 22, 2010; 74 FR 64840, December 8, 2009). The St. Louis study area included several counties and had population size and magnitudes of emissions density (on a spatial scale) similar to other urban areas in the U.S., while the second study area (Greene County, Missouri) was a rural county with much lower population and emissions density.

while at moderate or greater exertion (75 FR 35546-47, June 22, 2010). Results for the air quality scenario for a 1-hour standard level of 50 ppb suggested that such a standard would further limit exposures, such that more than 99%²⁹ of children at moderate or greater exertion would likely be protected from experiencing any days in a year with a 5-minute exposure at or above the 200 ppb benchmark concentration (75 FR 35542, June 22, 2010). In considering the implications of these estimates, and the substantial reduction in 5-minute exposures at or above 200 ppb, the Administrator did not judge that a standard level as low as 50 ppb³⁰ was warranted (75 FR 35547, June 22, 2010). Before reaching her conclusion with regard to level for the 1-hour standard, the Administrator additionally considered the epidemiologic evidence, placing relatively more weight on the U.S. epidemiologic studies (some conducted in multiple locations) reporting mostly positive and sometimes statistically significant associations between ambient SO₂ concentrations and emergency department visits or hospital admissions related to asthma or other respiratory symptoms, and noting a cluster of three studies for which 99th percentile 1-hour daily maximum concentrations were estimated to be between 78-150 ppb and for which the SO₂ effect estimate remained positive and statistically significant in copollutant models with PM (75 FR 35547-48, June 22, 2010).³¹

Given the above considerations and the comments received on the proposal, the

²⁹ The 2009 REA indicated this percentage to be 99.9% (2009 REA, Appendix B, p. B-62).

³⁰ In the 2009 REA results for the St. Louis single year scenario with a level of 50 ppb (the only level below 100 ppb that was analyzed), 99.9% of children with asthma would be expected to be protected from a day with a 5-minute exposure at or above 200 ppb, and 100% from a day with a 5-minute exposure at or above 400 ppb (2009 REA).

³¹ Regarding the monitor concentrations in these studies, the EPA noted that although they may be a reasonable approximation of concentrations occurring in the areas, the monitored concentrations were likely somewhat lower than the absolute highest 99th percentile 1-hour daily maximum SO₂ concentrations occurring across these areas (75 FR 35547, June 22, 2010).

Administrator judged, based on the entire body of evidence and information available in that review (concluded in 2010), and the related uncertainties,³² that a standard level of 75 ppb was appropriate. She concluded that such a standard, with a 1-hour averaging time and 99th percentile form, would provide a significant increase in public health protection compared to the then-existing standards and would be expected to provide protection, with an adequate margin of safety, against the respiratory effects elicited by SO₂ exposures in controlled human exposure studies and associated with ambient air concentrations in epidemiologic studies (75 FR 35548, June 22, 2010). The Administrator found that “a 1-hour standard at a level of 75 ppb is expected to substantially limit asthmatics’ exposure to 5–10 minute SO₂ concentrations \geq 200 ppb, thereby substantially limiting the adverse health effects associated with such exposures” (75 FR 35548, June 22, 2010). Such a standard was also considered likely “to maintain SO₂ concentrations below those in locations where key U.S. epidemiologic studies have reported that ambient SO₂ is associated with clearly adverse respiratory health effects, as indicated by increased hospital admissions and emergency department visits” (75 FR 35548, June 22, 2010). Lastly, the Administrator noted “that a standard level of 75 ppb is consistent with the consensus recommendation of CASAC” (75 FR 35548, June 22, 2010). The Administrator also considered the likelihood of public health benefits at lower standard levels, and judged a 1-hour standard at 75 ppb to be sufficient to protect public health with an adequate margin of safety (75 FR 35547-35548, June 22, 2010).

³² Such uncertainties included both those with regard to the epidemiologic evidence, including potential confounding and exposure error, and also those with regard to the information from controlled human exposure studies for at-risk groups, including the extent to which the results would be expected to be similar for individuals with more severe asthma than that in study subjects (75 FR 35546, June 22, 2010).

2. Approach for the Current Review

To evaluate whether it is appropriate to consider retaining the now current primary SO₂ standard, or whether consideration of revision is appropriate, the EPA has adopted an approach in this review that builds upon the general approach used in the last review and reflects the body of evidence and information now available. Accordingly, the approach in this review takes into consideration the approach used in the last review, addressing key policy-relevant questions in light of currently available scientific and technical information. As summarized above, the Administrator's decisions in the prior review were based on an integration of SO₂ health effects information with judgments on the adversity and public health significance of key health effects, policy judgments as to when the standard is requisite to protect against public health with an adequate margin of safety, consideration of CASAC advice, and consideration of public comments.

Similarly, in this review, we draw on the current evidence and quantitative assessments of exposure pertaining to the public health risk of SO₂ in ambient air. In considering the scientific and technical information here, we consider both the information available at the time of the last review and information newly available since the last review, including that which has been critically analyzed and characterized in the current ISA. The quantitative exposure and risk analyses provide a context for interpreting the evidence of lung function decrements in people with asthma breathing at elevated rates and the potential public health significance of exposures associated with air quality conditions that just meet the current standard.

B. Health Effects Information

The information summarized here is based on our scientific assessment of the health effects evidence available in this review; this assessment is documented in the ISA and its policy

implications are further discussed in the PA. More than 400 studies are newly available and considered in the ISA, including more than 200 health studies. They are consistent with the evidence that was available in the last review. As in the last review, the key evidence comes from the body of controlled human exposure studies that document effects in people with asthma. Policy implications of the currently available evidence are discussed in the PA (as summarized in section II.D.1 below). The subsections below briefly summarize the following aspects of the evidence: the nature of SO₂-related health effects (section II.B.1), the populations at risk (section II.B.2), exposure concentrations associated with health effects (section II.B.3), and potential public health implications (section II.B.4).

1. Nature of Effects

In this review, as in past reviews, the health effects evidence evaluated in the ISA for SO_x is focused on SO₂ (ISA, p. 5-1). As summarized in section I.D.1 above, atmospheric chemistry as well as emissions contribute to SO₂ being the most prevalent sulfur oxide in the atmosphere. As concluded in the ISA, “[o]f the sulfur oxides, SO₂ is the most abundant in the atmosphere, the most important in atmospheric chemistry, and the one most clearly linked to human health effects” (ISA, p. 2-1). Accordingly, the ISA states that “only SO₂ is present at concentrations in the gas phase that are relevant for chemistry in the atmospheric boundary layer and troposphere, and for human exposures” (ISA, p. 2-18). Thus, the current health effects evidence and the Agency’s review of the evidence, including the evidence newly available in this review, continues to focus on SO₂.

Sulfur dioxide is a highly reactive and water-soluble gas that once inhaled is absorbed

almost entirely in the upper respiratory tract³³ (ISA, sections 4.2 and 4.3). Short exposures to SO₂ can elicit respiratory effects, particularly in individuals with asthma (ISA, p. 1-17). Under conditions of elevated breathing rates (e.g., while exercising), SO₂ penetrates into the tracheobronchial region,³⁴ where, in sufficient concentration, it results in responses linked to asthma exacerbation in individuals with asthma (ISA, sections 4.2, 4.3, and 5.2). More specifically, bronchoconstriction,³⁵ which is characteristic of an asthma attack, is the most sensitive indicator of SO₂-induced lung function effects (ISA, p. 5-8). Associated with this bronchoconstriction response is an increase in airway resistance which is an index of airway hyperresponsiveness (AHR).³⁶ Exercising individuals without asthma have also been found to exhibit such responses, but at much higher SO₂ exposure concentrations (ISA, section 5.2.1.7). For example, the ISA finds that “healthy adults are relatively insensitive to the respiratory effects of SO₂ below 1 ppm” (ISA, p. 5-9).

Based on assessment of the currently available evidence, as in the last review, the ISA concludes that there is a causal relationship between short-term SO₂ exposures (as short as a few minutes) and respiratory effects (ISA, section 5.2.1). The clearest evidence for this causal relationship comes from the long-standing evidence base of controlled human exposure studies

³³ The term “upper respiratory tract” refers to the portion of the respiratory tract, including the nose, mouth and larynx, that precedes the tracheobronchial region (ISA, sections 4.2 and 4.3).

³⁴ The term “tracheobronchial region” refers to the region of the respiratory tract subsequent to the larynx and preceding the deep lung (or alveoli). This region includes the trachea and bronchii.

³⁵ The term bronchoconstriction refers to constriction or narrowing of the airways in the respiratory tract.

³⁶ Airway hyperresponsiveness, which is an increased propensity of the airways to narrow in response to bronchoconstrictive stimuli, is a characteristic feature of people with asthma (ISA, section 5.2.1.2).

(U.S. EPA, 1994; 2008 ISA). These studies demonstrate asthma exacerbation-related lung function decrements³⁷ and respiratory symptoms (e.g., cough, chest tightness and wheeze) in people with asthma exposed to SO₂ for 5 to 10 minutes at elevated breathing rates (ISA, section 5.2.1). Bronchoconstriction, evidenced by decrements in lung function, that are sometimes accompanied by respiratory symptoms (e.g., cough, wheeze, chest tightening and shortness of breath), is observed to occur in these studies at SO₂ concentrations as low as 200 ppb in some people with asthma exposed while breathing at elevated rates, such as during exercise (ISA, section 5.2.1.2).³⁸ In contrast, respiratory effects are not generally observed in other people with asthma (nonresponders) and healthy adults exposed, while exercising, to SO₂ concentrations below 1000 ppb (ISA, sections 5.2.1.2 and 5.2.1.7). Across studies, bronchoconstriction in response to SO₂ exposure is mainly seen during conditions of elevated breathing rates, such as exercise or with mouthpiece exposures that involve laboratory-facilitated rapid, deep breathing.³⁹ With these conditions, breathing shifts from nasal breathing to oral/nasal breathing, which increases the concentrations of SO₂ reaching the tracheobronchial region of lower airways, where, depending on dose and the exposed individual's susceptibility, it may cause bronchoconstriction (ISA, sections 4.1.2.2, 4.2.2, and 5.2.1.2).

³⁷ The specific responses reported in the evidence base that are described in the ISA as lung function decrements are increased specific airway resistance (sRaw) and reduced forced expiratory volume in 1 second (FEV₁) (ISA, section 5.2.1.2).

³⁸ The data from controlled human exposure studies of people with asthma indicate that there are two subpopulations that differ in their airway responsiveness to SO₂, with the second subpopulation being insensitive to SO₂ bronchoconstrictive effects at concentrations as high as 1000 ppb (ISA, pp. 5-14 to 5-21; Johns et al., 2010).

³⁹ Laboratory-facilitated rapid deep breathing involves rapid, deep breathing through a mouthpiece that provides a mixture of oxygen with enough carbon dioxide to prevent an imbalance of gases in the blood usually resulting from hyperventilation. Breathing in the laboratory with this technique is referred to as eucapnic hypernea.

The evidence base of controlled human exposure studies for people with asthma⁴⁰ is the same in this review as in the last review. Such studies reporting asthma exacerbation-related effects for individuals with asthma are summarized in Tables 5-1 and 5-2, as well as section 5.2.1.2 of the ISA. The main responses observed include increases in specific airway resistance (sRaw) and reductions in forced expiratory volume in one second (FEV₁) after 5- to 10-minute exposures. As recognized in the last review, the results of these studies indicate that among individuals with asthma, some individuals have a greater response to SO₂ than others or a measurable response at lower exposure concentrations (ISA, p. 5-14). The SO₂-induced bronchoconstriction in these studies occurs rapidly, in as little as two minutes from exposure start, and is transient, with recovery occurring upon cessation of exposure (ISA, p. 5-14; Table 5-2).

The epidemiologic evidence, some of which is newly available since the time of the last review, includes studies reporting positive associations for asthma-related hospital admissions of children or emergency department visits by children with short-term SO₂ exposures (ISA, section 5.2.1). These findings provide evidence supportive of the EPA's conclusion of a causal relationship between short-term SO₂ exposures and respiratory effects, for which the controlled human exposure studies are the primary basis (ISA, section 5.2.1.9). With regard to newly available epidemiologic studies, there are a limited number of such studies that have investigated SO₂ effects related to asthma exacerbation, with the most supportive evidence coming from studies on asthma-related emergency department visits by children and hospital admissions of

⁴⁰ The subjects in these studies have primarily been adults. The exception has been a few studies conducted in adolescents aged 12 to 18 years of age (ISA, pp. 5-22 to 5-23; PA, sections 3.2.1.3 and 3.2.1.4).

children (ISA, section 5.2.1.2). As in the last review, areas of uncertainty in the epidemiologic evidence relate to the characterization of exposure through the use of fixed site monitor concentrations as surrogates for population exposure (often over a substantially sized area and for durations greater than an hour) and the potential for confounding by PM⁴¹ or other copollutants (ISA, section 5.2.1). In general, the pattern of associations across the newly available studies is consistent with the studies available in the last review (ISA, p. 5-75).

The evidence base for long-term⁴² SO₂ exposure and respiratory effects is somewhat augmented since the last review such that the ISA in the current review concludes it to be suggestive of, but not sufficient to infer, a causal relationship (ISA, section 5.2.2). The support for this conclusion comes mainly from the limited epidemiologic study findings of associations between long-term SO₂ concentrations and increases in asthma incidence combined with findings of laboratory animal studies involving newborn rodents that indicate a potential for SO₂ exposure to contribute to the development of asthma, especially allergic asthma, in children (ISA, section 1.6.1.2). The evidence showing increases in asthma incidence is coherent with results of animal toxicological studies that provide a pathophysiologic basis for the development of asthma. The overall body of evidence, however, lacks consistency (ISA, section 1.6.1.2). Further, there are uncertainties that apply to the epidemiologic evidence, including newly available evidence, across the respiratory effects examined for long-term exposure (ISA, section 5.2.2.7).

For effects other than respiratory effects, the current evidence is generally similar to the

⁴¹ The potential for confounding by PM is of particular interest given that SO₂ is a precursor to PM (ISA, p. 1-7).

⁴² In evaluating the health effects studies in the ISA, the EPA has generally categorized exposures of durations longer than a month as “long-term” (ISA, p. 1-2).

evidence available in the last review, and leads to similar conclusions. With regard to a relationship between short-term SO₂ exposure and total mortality, the ISA reaches the same conclusion as the previous review that the evidence is suggestive of, but not sufficient to infer, a causal relationship (ISA, section 5.5.1). This conclusion is based on the evidence of previously and newly available multicity epidemiologic studies that provide consistent evidence of positive associations coupled with uncertainty regarding the potential for SO₂ to have an independent effect on mortality. While recent studies have analyzed some key uncertainties and data gaps from the previous review, uncertainties still exist, given the limited number of studies that examined copollutant confounding, the evidence for a decrease in the size of SO₂-mortality associations in copollutant models with nitrogen dioxide and particulate matter with mass median aerodynamic diameter below 10 microns, and the lack of a potential biological mechanism for mortality following short-term SO₂ exposures (ISA, section 1.6.2.4).

For other categories of health effects,⁴³ the currently available evidence is inadequate to infer the presence or absence of a causal relationship, mainly due to inconsistent evidence across specific outcomes and uncertainties regarding exposure measurement error, copollutant confounding, and potential modes of action (ISA, sections 5.3.1, 5.3.2, 5.4, 5.5.2, 5.6). These conclusions are consistent with those made in the previous review (ISA, p. xlviii).

Thus, the current health effects evidence supports the primary conclusion that short-term exposure to SO₂ in ambient air causes respiratory effects, in particular, asthma exacerbation in individuals with asthma; this evidence and these conclusions are also consistent with that

⁴³ The other categories evaluated in the ISA include cardiovascular effects with short- or long-term exposures; reproductive and developmental effects; and cancer and total mortality with long-term exposures (ISA, section 1.6.2 and Table 1-1).

available in the last review. The focus in this review, as in prior reviews, is on such effects.

2. At-risk Populations

In this document, we use the term “at-risk populations”⁴⁴ to recognize populations that have a greater likelihood of experiencing SO₂-related health effects, *i.e.* groups with characteristics that contribute to an increased risk of SO₂-related health effects. In identifying factors that increase risk of SO₂-related health effects, we have considered evidence regarding factors contributing to increased susceptibility, which generally include intrinsic factors, such as physiological factors that may influence the internal dose or toxicity of a pollutant, or extrinsic factors, such as sociodemographic or behavioral factors (ISA, p. 6-1).

The information newly available in this review has not substantially altered our previous understanding of at-risk populations for SO₂ in ambient air. As in the last review, people with asthma are at increased risk for SO₂-related health effects, specifically for respiratory effects, and specifically asthma exacerbation elicited by short-term exposures while breathing at elevated rates (ISA, sections 5.2.1.2 and 6.3.1). This conclusion of the at-risk status of people with asthma is based on the well-established and well-characterized evidence from controlled human exposure studies, supported by the evidence on mode of action for SO₂ with additional support from epidemiologic studies (ISA, sections 5.2.1.2 and 6.3.1). Somewhat similar to the conclusion in the last review that children and older adults are potentially susceptible populations, the ISA (relying on a framework for evaluating the evidence for risk factors that has been developed

⁴⁴ As noted in section I above, we use the term “at-risk populations” to refer to persons having a quality or characteristic in common, such as a specific pre-existing illness or a specific age or lifestyle for which there is an increased risk of SO₂-related health effects.

since the last review)⁴⁵ indicates the evidence to be suggestive of increased risk for these groups, with some limitations and inconsistencies (ISA, sections 6.5.1.1 and 6.5.1.2).⁴⁶

Children with asthma, however, may be particularly at risk compared to adults with asthma (ISA, section 6.3.1). This conclusion reflects several characteristics of children as compared to adults, which include their greater responsiveness to methacholine,⁴⁷ a chemical that can elicit bronchoconstriction in people with asthma, as well as their greater use of oral breathing, particularly by boys (ISA, sections 5.2.1.2 and 4.1.2). Oral breathing (vs. nasal breathing) and increased breathing rate are factors that allow for greater SO₂ penetration into the tracheobronchial region of the lower airways, and reflect conditions of individuals with asthma in which bronchoconstriction-related responses have been observed in the controlled exposure studies (ISA, sections 4.2.2, 5.2.1.2, and 6.3.1). Although the epidemiological evidence includes

⁴⁵ Since the 2010 review of the primary SO₂ NAAQS, the EPA has developed a formal framework to transparently characterize the strength of the evidence that can inform the identification of populations and lifestages at increased risk of a health effect related to exposure to a pollutant. This framework is part of the systematic approach taken in the ISA for this review (ISA, section 6.2).

⁴⁶ The current evidence for risk to older adults relative to other lifestages comes from epidemiologic studies, for which findings are somewhat inconsistent, and studies with which there are uncertainties in the association with the health outcome (ISA, section 6.5.1.2).

⁴⁷ The ISA concluded that potential differences in airway responsiveness of children to SO₂ relative to adolescents and adults may be inferred by differences in responses to methacholine (ISA, section 5.2.1.2). Methacholine is a chemical that can elicit bronchoconstriction through its action on airway smooth muscle receptors. It is commonly used to identify people with asthma and accordingly has been used to screen subjects for studies of SO₂ effects. However, results of studies of the extent to which airway response to methacholine is predictive of SO₂ responsiveness have varied somewhat. For example, an analysis of the extent to which airway responsiveness to methacholine, a history of respiratory symptoms, and atopy were significant predictors of airway responsiveness to SO₂, found that about 20 to 25% of subjects ranging in age from 20 to 44 years that were hyperresponsive to methacholine were also hyperresponsive to SO₂ (ISA, section 5.2.1.2; Nowak et al., 1997). Another study focused on individuals with airway responsiveness to methacholine found only a weak correlation between airway responsiveness to SO₂ and methacholine (ISA, section 5.2.1.2; Horstman et al., 1986).

a number of studies focused on health outcomes in children that are supportive of the qualitative conclusions of causality (ISA, section 5.2.1.2), there are few controlled human exposure studies to inform our understanding of exposure concentrations associated with effects in this population group. Those studies have not included subjects younger than 12 years (ISA, p. 5-22). Some characteristics particular to school-age children younger than 12 years, such as increased propensity for mouth breathing (ISA, p. 4-5), however, suggest that this age group of children with asthma might be expected to experience larger lung function decrements than adults with asthma (ISA, p. 5-25).⁴⁸

Additionally, some individuals with asthma have a greater response to SO₂ than others with similar disease status (ISA, section 5.2.1.2; Horstman et al., 1986; Johns et al., 2010). This occurrence is quantitatively analyzed in a study newly available in this review. This study examined differences in lung function response using individual subject data available from five studies of individuals with asthma exposed to multiple concentrations of SO₂ for 5 to 10 minutes while breathing at elevated rates (Johns et al., 2010). As noted in the ISA, “these data demonstrate a bimodal distribution of airway responsiveness to SO₂ in individuals with asthma, with one subpopulation that is insensitive to the bronchoconstrictive effects of SO₂ even at concentrations as high as 1.0 ppm, and another subpopulation that has an increased risk for bronchoconstriction at low concentrations of SO₂” (ISA, p. 5-20). While such information

⁴⁸ The ISA does not find the evidence to be adequate to conclude differential risk status for subgroups of children with asthma (ISA, Chapter 6). In consideration of the limited information regarding factors related to breathing habit, however, and recognizing the lack of evidence from controlled human exposure studies of SO₂-induced lung function decrements in children, approximately 5 to 11 years of age, with asthma, the ISA suggests that this age group of children and “particularly boys and perhaps obese children, might be expected to experience greater responsiveness (i.e., larger decrements in lung function) following exposure to SO₂ than normal-weight adolescents and adults” (ISA, p. 4-7 and 5-36).

provides documentation that some individuals have a greater response to SO₂ than others with the same disease status, the factors contributing to this greater susceptibility are not yet known (ISA, pp. 5-14 to 5-21).

The current evidence for factors evaluated in the ISA other than asthma status and lifestyle is inadequate to determine whether they (e.g., sex and SES) might have an influence on risk of SO₂-related effects (ISA, section 6.6).

3. Exposure Concentrations Associated with Health Effects

Our understanding of exposure duration and concentrations associated with SO₂-related health effects is largely based, as it was in the last review, on the longstanding evidence base of controlled human exposure studies. These studies demonstrate a dose-response relationship between 5- and 10-minute SO₂ exposure concentrations and decrements in lung function (e.g., increased sRaw and reduced FEV₁) and occurrence of respiratory symptoms in individuals with asthma exposed while breathing at elevated rates (ISA, section 1.6.1.1). Clear and consistent increases in these effects occur with increasing SO₂ exposure (ISA, Table 5-2 and pp. 5-35, 5-39). Further, the SO₂-induced bronchoconstriction occurs rapidly; exposures as short as 5 minutes have been found to elicit a similar bronchoconstrictive response as somewhat longer exposures. For example, during exposure to SO₂ over a 30-minute period with continuous exercise, the response to SO₂ has been found to develop rapidly and is maintained throughout the 30-minute exposure (ISA, p. 5-14). In a study involving short exercise periods within a 6-hour exposure period, the effects observed following exercise were documented to return to baseline levels within one hour after the cessation of exercise, even with continued exposure (ISA, p. 5-14; Linn et al., 1984). Thus, the controlled human exposure evidence base demonstrates the

occurrence of SO₂-related effects as a result of peak exposures on the order of minutes.⁴⁹

The controlled human exposure study findings⁵⁰ demonstrate that SO₂ concentrations as low as 200 to 300 ppb for 5 to 10 minutes elicited moderate or greater lung function decrements, measured as a decrease in FEV₁ of at least 15% or an increase in sRaw of at least 100%, in the study subjects (ISA, sections 1.6.1.1 and 5.2.1). The percent of individuals affected, the severity of response, and the accompanying occurrence of respiratory symptoms increased with increasing SO₂ exposure concentrations (ISA, section 5.2.1). At concentrations ranging from 200 to 300 ppb, the lowest levels for which the ISA describes SO₂-related lung function decrements (in terms of 15% reductions in FEV₁ or doubling or tripling of sRaw), as many as 33% of exercising study subjects with asthma experienced moderate or greater decrements in lung function (ISA, section 5.2.1, Table 5-2). Analyses focused on subjects with asthma in multiple studies that are responsive to SO₂ at exposure concentrations below 1000 ppb found there to be statistically significant increases in lung function decrements occurring at 300 ppb (ISA, p. 153; Johns et al., 2010). At concentrations at or above 400 ppb, moderate or greater decrements in lung function occurred in 20 to 60% of exercising individuals with asthma and a larger percentage of individuals with asthma experienced more severe decrements in lung function (i.e., an increase in sRaw of at least 200%, and/or a 20% or more decrease in FEV₁), compared to

⁴⁹ As the air quality metrics in the epidemiologic studies are for time periods longer than the 5- to 10-minute exposures eliciting effects in the controlled human exposure studies, these studies may not adequately capture the spatial and temporal variation in SO₂ concentrations and cannot address whether observed associations of asthma-related emergency room visits or hospital admissions with 1-hour to 24-hour ambient air concentration metrics are indicative of a potential response to exposure on the order of hours or much shorter-term exposure to peaks in SO₂ concentration (ISA, pp. 5-49, 5-59, 5-25).

⁵⁰ The findings summarized in Table 5-2 of the ISA and in Table 3-1 of the PA are based on results that have been adjusted for effects of exercise in clean air so that they have separated out any effect of exercise in causing bronchoconstriction and reflect only the SO₂-specific effect.

exposures at 200 to 300 ppb (ISA, section 5.2.1.2, p. 5-9 and Table 5-2). Additionally, at concentrations at or above 400 ppb, moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5-2 and section 5.2.1).

The lowest exposure concentration for which individual study subject data are available in terms of the sRaw and FEV₁ from studies that have assessed the SO₂ effect *versus* the effect of exercise in clean air is 200 ppb (ISA, Table 5-2 and Figure 5-1). In nearly all of these studies (and all of the studies for concentrations below 500 ppb), study subjects breathed freely (e.g., without using a mouthpiece).⁵¹ In studies that tested 200 ppb, a portion of the exercising study subjects with asthma (approximately 8 to 9%) responded with at least a doubling in sRaw or an increase in FEV₁ of at least 15% (ISA, Table 5-2 and Figure 5-2; PA, Table 3-1; Linn et al., 1983a; Linn et al., 1987).

With regard to exposure concentrations below 200 ppb, the very limited available evidence is for exposure as low as 100 ppb. Some differences in methodology and the reporting of results complicate comparisons of the studies of 100 ppb exposure with studies of higher concentrations. In the studies testing this concentration, subjects were exposed by mouthpiece rather than freely breathing in an exposure chamber (Sheppard et al., 1981; Sheppard et al., 1984; Koenig et al., 1989; Koenig et al., 1990; Trenga et al., 2001; ISA, section 5.2.1.2; PA, section 3.2.1.3). Additionally, only a few of these studies included an exposure to clean air while

⁵¹ Studies of free-breathing subjects generally make use of small rooms in which the atmosphere is experimentally controlled such that study subjects are exposed by freely breathing the surrounding air (e.g., Linn et al., 1987).

exercising that would have allowed for determining the effect of SO₂ *versus* the effect of exercise in causing bronchoconstriction (Sheppard et al., 1981, 1984; Koenig et al., 1989). In those cases, a limited number of adult and adolescent study subjects were reported to experience small changes in sRaw, with the magnitudes of change appearing to be smaller than responses reported from studies at exposure concentrations of 200 ppb or more.⁵² ⁵³Thus, the set of studies for the 100 ppb exposure concentration, while limited and complicated by differences from studies of higher concentrations with regard to reporting of results and exposure method, does not indicate this exposure concentration to result in as much as a doubling in sRaw, based on the extremely few adults and adolescents tested (Sheppard et al., 1981, 1984; Koenig et al., 1989).

Specific exposure concentrations that may be eliciting respiratory responses are not available from the epidemiological studies that find associations with outcomes such as asthma-related emergency department visits and hospitalizations. For example, in noting limitations of epidemiologic studies with regard to uncertainties in SO₂ exposure estimates, the ISA recognized that “[it] is unclear whether SO₂ concentrations at the available fixed site monitors adequately

⁵² For example, the increase in sRaw reported for two young adult subjects exposed to 100 ppb in the study by Sheppard et al. (1981) was slightly less than half the response of these subjects at 250 ppb, and the results for the study by Sheppard et al. (1984) indicate that none of the eight study subjects experienced as much as a doubling in sRaw in response to the mouthpiece exposure to 125 ppb while exercising. In the study of adolescents (aged 12 to 18 years), among the three individual study subjects for which respiratory resistance appears to have increased with SO₂ exposure, the magnitude of any increase after consideration of the response to exercise appears to be less than 100% in each subject (Koenig et al., 1989).

⁵³ In a mouthpiece exposure system, the inhaled breath completely bypasses the nasal passages where SO₂ is efficiently removed, thus allowing more of the inhaled SO₂ to penetrate into the tracheobronchial airways (2008 ISA, p. 3-4; ISA, section 4.1.2.2). This allowance of greater penetration of SO₂ into the tracheobronchial airways, as well as limited evidence comparing responses by mouthpiece and chamber exposures, leads to the expectation that SO₂-responsive people with asthma breathing SO₂ using a mouthpiece, particularly while breathing at elevated rates, would experience greater lung function responses than if exposed to the same test concentration while freely breathing in an exposure chamber (ISA, p. 5-23; Linn et al., 1983b).

represent variation in personal exposures especially if peak exposures are as important as indicated by the controlled human exposure studies” (ISA, p. 5-37). This extends the observation of the 2008 ISA that “it is possible that these epidemiologic associations are determined in large part by peak exposures within a 24-h[our] period” (2008 ISA, p. 5-5). Given the important role of SO₂ as a precursor to PM in ambient air, however, a key uncertainty in the epidemiologic evidence available in this review, as in the last review, is potential confounding by copollutants, particularly PM (ISA, p. 5-5). Among the U.S. epidemiologic studies reporting mostly positive and sometimes statistically significant associations between ambient SO₂ concentrations and emergency department visits or hospital admissions (some conducted in multiple locations), few studies have attempted to address this uncertainty, e.g., through the use of copollutant models. For example, as in the last review, there are three U.S. studies for which the SO₂ effect estimate remained positive and statistically significant in copollutant models with PM.⁵⁴ No additional such studies have been newly identified in this review that might inform this issue. Thus, such uncertainties regarding copollutant confounding, as well as exposure measurement error, remain in the currently available epidemiologic evidence base (ISA, p. 5-6).

4. Potential Impacts on Public Health

In general, the magnitude and implications of potential impacts on public health are dependent upon the type and severity of the effect, as well as the size and other features of the population affected (ISA, section 1.7.4; PA, 3.2.1.5). With regard to SO₂ concentrations in ambient air, the public health implications and potential public health impacts relate to the

⁵⁴ Based on data available for specific time periods at some monitors in the areas of these studies, the 99th percentile 1-hour daily maximum concentrations were estimated in the last review to be between 78-150 ppb (Thompson and Stewart, 2009; PA, Appendix D).

effects causally related to SO₂ exposures of interest in this review. These are respiratory effects of short-term exposures, and particularly those effects associated with asthma exacerbation in people with asthma. As summarized above in section II.B.1, the most strongly demonstrated effects are bronchoconstriction-related effects resulting in decrements in lung function elicited by short term exposures during periods of elevated breathing rate; asthma-related health outcomes such as emergency department visits and hospital admissions have also been statistically associated with ambient air SO₂ concentration metrics in epidemiologic studies (ISA, section 5.2.1.9).

As summarized in section II.B.2 above, people with asthma are the population at risk for SO₂-related effects and children with asthma are considered to be at relatively greater risk than other age groups within this at-risk population (ISA, section 6.3.1). The evidence supporting this conclusion comes primarily from studies of individuals with mild to moderate asthma,⁵⁵ with very little evidence available for individuals with severe asthma. The evidence base of controlled human exposure studies of exercising people with asthma provides very limited information indicating that there are similar responses (in terms of relative decrements in lung function in

⁵⁵ These studies categorized asthma severity based mainly on the individual's use of medication to control asthma, such that individuals not regularly using medication were classified as minimal/mild, and those regularly using medication as moderate/severe (Linn et al., 1987). The ISA indicates that the moderate/severe grouping would likely be classified as moderate by today's asthma classification standards due to the level to which their asthma was controlled and their ability to engage in moderate to heavy levels of exercise (ISA, p. 5-22; Johns et al., 2010; Reddel, 2009).

response to SO₂ exposures) of individuals with differences in severity of their asthma.⁵⁶

However, the two available studies “suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5-22; Linn et al., 1987; Trenga et al., 1999). Consideration of such baseline differences among members of at-risk populations and of the relative transience or persistence of these responses (e.g., as noted in section II.B.3 above), as well as other factors, is important to characterizing implications for public health, as recognized by the ATS in their recent statement on evaluating adverse health effects of air pollution (Thurston et al., 2017).

The Administrator’s judgment is informed by statements by the ATS on what constitutes an adverse health effect of air pollution. Building on the earlier statement by the ATS that was considered in the last review (ATS, 2000), the recent policy statement by the ATS on what constitutes an adverse health effect of air pollution provides a general framework for interpreting evidence that proposes a “set of considerations that can be applied in forming judgments” for this context (Thurston et al., 2017). The earlier ATS statement, in addition to emphasizing clinically relevant effects (e.g., the adversity of small transient changes in lung function metrics in combination with respiratory symptoms), also emphasized both the need to consider changes in “the risk profile of the exposed population” and effects on the portion of the population that may

⁵⁶ The ISA identifies two studies that have investigated the influence of asthma severity on responsiveness to SO₂, with one finding that a larger change in lung function observed in the moderate/severe asthma group was attributable to the exercise component of the study protocol while the other did not assess the role of exercise in differences across individuals with asthma of differing severity (Linn et al., 1987; Trenga et al., 1999). The ISA states, “[h]owever, both studies suggest that adults with moderate/severe asthma may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5-22). Based on the criteria used in the study by Linn et al (1987) for placing individuals in the “moderate/severe” group, the ISA concluded that the asthma of these individuals “would likely be classified as moderate by today’s classification standards” (ISA, p. 5-22; Johns et al., 2010; Reddel, 2009).

have a diminished reserve that could put its members at potentially increased risk of effects from another agent (ATS, 2000). The consideration of effects on individuals with preexisting diminished lung function continues to be recognized as important in the more recent ATS statement (Thurston et al., 2017). For example, in adding emphasis in this area, this statement conveys the view that “small lung function changes” in individuals with compromised function, such as that resulting from asthma, should be considered adverse, even without accompanying respiratory symptoms (Thurston et al., 2017). All of these concepts, including the consideration of the magnitude of effects occurring in just a subset of study subjects, are recognized as important in the more recent ATS statement (Thurston et al., 2017) and continue to be relevant to consideration of the evidence base for SO₂.

Such concepts are routinely considered by the Agency in weighing public health implications for decisions on primary NAAQS, as summarized in section I.A above. For example, in deliberations on a standard that provides the requisite public health protection under the Act, the EPA traditionally recognizes the nature and severity of the health effects involved, recognizing the greater public health significance of more severe health effects, including, for example, effects that have been documented to be accompanied by symptoms, and of the risk of repeated occurrences of effects (76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Another area of consideration is characterization of the population at risk, including its size and, as pertinent, the exposure/risk estimates in this regard. Such factors related to public health significance, and the kind and degree of associated uncertainties, are considered by the EPA in addressing the CAA requirement that the primary NAAQS are requisite to protect public health, including a margin of safety, as summarized in section I.A above.

Ambient air concentrations of SO₂ vary considerably in areas near sources, but

concentrations in the vast majority of the U.S. are well below the current standard (PA, Figure 2-7). Thus, while the population counts discussed below may convey information and context regarding the size of populations living near sizeable sources in some areas, the concentrations in most areas of the U.S. are well below the conditions assessed in the REA.

With regard to the size of the U.S. population at risk of SO₂-related effects, the National Center for Health Statistics data from the 2015 National Health Interview Survey (NHIS)⁵⁷ indicate that approximately 8% of the U.S. population has asthma (PA, Table 3-2; CDC, 2017). Among all U.S. adults, the prevalence is estimated to be 7.6%, with women having a higher estimate (9.7%) than men (5.4%). The estimated prevalence is greater in children (8.4% for children less than 18 years of age) than adults (7.6%) (PA, Table 3-2; CDC, 2017). Asthma was the leading chronic illness affecting children in 2012, the most recent year for which such an evaluation is available (Bloom et al., 2013). As noted in the PA, there are more than 24 million people with asthma currently in the U.S., including more than 6 million children (PA, sections 3.2.2.4 and 3.2.4).

Relatively greater population-level SO₂ impacts (i.e., greater numbers of individuals affected) might be expected in population groups with relatively greater asthma prevalence (i.e., groups with relatively higher percentages of individuals that have asthma). Among all U.S.

⁵⁷ The NHIS is conducted annually by the U.S. Centers for Disease Control and Prevention. The NHIS collects health information from a nationally representative sample of the noninstitutionalized U.S. civilian population through personal interviews. Participants (or parents of participants if the survey participant is a child) who have ever been told by a doctor or other health professional that the participant had asthma and reported that they still have asthma were considered to have current asthma. Data are weighted to produce nationally representative estimates using sample weights; estimates with a relative standard error greater than or equal to 30% are generally not reported (Mazurek and Syamlal, 2018). The NHIS estimates described here are drawn from the 2015 NHIS, Table 4-1 (<https://www.cdc.gov/asthma/nhis/2015/table4-1.htm>).

children, the asthma prevalence estimate is greater for boys than girls (CDC, 2017). Asthma prevalence estimates from the 2015 NHIS vary for children of different races or ethnicities and household income, among other factors (CDC, 2017). Among populations of different races or ethnicities, black non-Hispanic and Puerto Rican Hispanic children are estimated to have the highest prevalences, at 13.4% and 13.9%, respectively. Asthma prevalence is also increased among populations in poverty, with the prevalence estimated to be 11.1% among people living in households below the poverty level compared to 7.2% of those living above it.

The information on which to base estimates of asthma prevalence in other subgroups of children is much more limited (e.g., as discussed in the REA, section 4.1.2). For example, the more limited information from the NHIS for 2011-2015 indicates there to be a greater prevalence of asthma in children that are obese⁵⁸ compared to those that are not (REA, section 4.1.2, Figure 4-2).⁵⁹

With regard to the potential for exposure of the populations at risk from exposures to SO₂ in ambient air, the PA recognizes that while SO₂ concentrations have generally declined across the U.S. since 2010 when the current standard was set (PA, Figures 2-5 and 2-6), there are

⁵⁸ Although the CDC does not report NHIS estimates for the percent of obese adults or children that have asthma, they do report that more adults with asthma are obese than adults without asthma. As discussed in the REA, the NHIS sample size for children with asthma identified as obese is very limited (REA, section 4.1.2).

⁵⁹ In consideration of the limited information regarding factors related to breathing habit (whether one is breathing through their nose or mouth) and recognizing the lack of evidence from controlled human exposure studies of SO₂-induced lung function decrements in children, approximately 5 to 11 years of age, with asthma, the ISA suggests that this age group of children and “particularly boys and perhaps obese children, might be expected to experience greater responsiveness (i.e., larger decrements in lung function) following exposure to SO₂ than normal-weight adolescents and adults” (ISA, pp. 4-7 and 5-36). However, the ISA does not find the evidence to be adequate to conclude differential risk status for subgroups of children with asthma (ISA, Chapter 6).

numerous areas where SO₂ concentrations still contribute to air quality that is near or above the standard. For example, the most recently available design values for the primary SO₂ standard (those based on monitoring data for the 2014-2016 period) indicate there to be 15 core-based statistical areas⁶⁰ with design values above the existing standard level of 75 ppb, of which a number have sizeable populations.⁶¹ In addition to this evidence of elevated ambient air SO₂ concentrations, there are limitations in the monitoring network with regard to the extent that it might be expected to capture all areas with the potential to exceed the standard (e.g., 75 FR 35551; June 22, 2010).⁶² In recognition of these limitations, the PA also examined the proximity of populations to sizeable SO₂ point sources using the most recently available emissions

⁶⁰ Core-based statistical area (CBSA) is a geographic area defined by the U.S. Office of Management and Budget to consist of an urban area of at least 10,000 people in combination with its surrounding or adjacent counties (or equivalents) with which there are socioeconomic ties through commuting (https://www.census.gov/geo/reference/gtc/gtc_cbsa.html). Populations in the 15 CBSAs referred to in the body of the text range from approximately 30,000 to more than a million (based on 2016 U.S. Census Bureau estimates).

⁶¹ Table 5c. Monitoring Site Listing for Sulfur Dioxide 1-Hour NAAQS in the Excel file labeled So2_designvalues_20142016_final_07_19_16.xlsx downloaded from <https://www.epa.gov/air-trends/air-quality-design-values> on January 26, 2018.

⁶² As state and local air agencies have the flexibility to characterize air quality using either modeling of actual source emissions or using appropriately sited ambient air monitors for designation purposes, both types of information have been used to support designations of areas not meeting the standard. To date, 42 areas have been designated as nonattainment areas, although air quality improvements in two of these 42 areas has led to the areas meeting the standard and being redesignated. The population residing in the remaining 40 nonattainment areas is approximately 3.3 million people (see <https://www3.epa.gov/airquality/greenbook/tnsum.html>). Detailed information about source types in these areas can be found in the technical support documents for individual nonattainment areas, available via <https://www.epa.gov/sulfur-dioxide-designations/sulfur-dioxide-designations-regulatory-actions>. These areas generally had significant SO₂ point sources, with the majority of these point sources being electric generating units.

inventory information (2014), which is also characterized in the ISA (ISA, section 2.2.2).⁶³ This information indicates that there are more than 300,000 and 60,000 children living within 1 km of facilities emitting at least 1,000 and 2,000 tpy of SO₂, respectively. Within 5 km of such sources, the numbers are approximately 1.4 million and 700,000, respectively (PA, Table 3-5). While information on SO₂ concentrations in locations of maximum impact of such sources is not available for all these areas, and SO₂ concentrations vary appreciably near sources, simply considering the 2015 national estimate of asthma prevalence of approximately 8% (noted above), this information would suggest there may be as many as 24,000 to more than 100,000 children with asthma that live in areas near substantially sized sources of SO₂ emissions to ambient air (PA, section 3.2.1.5; Table 3-5).

The information discussed in this section indicates the potential for exposures to SO₂ in ambient air to be of public health importance. Such considerations contributed to the basis for the 2010 decision to appreciably strengthen the primary SO₂ NAAQS and to establish a 1-hour standard to provide the requisite public health protection for at-risk populations from short-term exposures of concern.

C. Summary of Risk and Exposure Information

Our consideration of the scientific evidence available in the current review (summarized in section II.B above), as at the time of the last review, is informed by results from a quantitative analysis of estimated population exposure and associated risk of bronchoconstriction-related

⁶³ Although source characteristics and meteorological conditions - in addition to magnitude of emissions - influence the distribution of concentrations in ambient air, these estimates are based on proximity to large sources, rather than ambient concentrations, due to limitations in the available information with regard to spatial (and temporal) patterns of SO₂ concentrations in the proximity of such sources in urban areas (ISA, section 2.5.2.2).

effects that the evidence indicates to be elicited in some portion of exercising people with asthma by short exposures to elevated SO₂ concentrations, e.g., such exposures lasting 5 or 10 minutes. This analysis, for the air quality scenario of just meeting the current standard, estimates two types of risk metrics in terms of percentages of the simulated at-risk populations of adults with asthma and children with asthma (REA, section 4.6). The first of the two risk metrics is based on comparison of the estimated 5-minute exposure concentrations for individuals breathing at elevated rates to 5-minute exposure concentrations of potential concern (benchmark concentrations), and the second utilizes exposure-response (E-R) information from studies in which subjects experienced moderate or greater lung function decrements (specifically a doubling or more in sRaw) to estimate the portion of the simulated at-risk population likely to experience one or more days with an SO₂-related increase in sRaw of at least 100% (REA, sections 4.6.1 and 4.6.2). Both of these metrics are used in the REA to characterize health risk associated with 5-minute peak SO₂ exposures among simulated at-risk populations during periods of elevated breathing rates. These risk metrics were also derived in the REA for the last review and the associated estimates informed the Administrator's 2010 decision to establish the current standard (75 FR 35546-35547, June 22, 2010).

The following subsections summarize key aspects of the design and methods of the quantitative assessment (section II.C.1) and the important uncertainties associated with these analyses (section II.C.2). The results of the analyses are summarized in section II.C.3.

1. Key Design Aspects

In this section, we provide an overview of key aspects of the quantitative exposure and risk assessment conducted for this review, including the study areas, air quality adjustment approach, modeling tools, at-risk populations simulated, and benchmark concentrations assessed.

The assessment is described in detail in the REA and summarized in section 3.2.2 of the PA.

Given the primary overarching consideration in this review of whether the currently available information calls into question the adequacy of protection provided by the current standard, the air quality scenario analyzed in the REA focuses on air quality conditions that just meet the current standard. With this focus, the analyses estimate exposure and risk for at-risk populations in three urban study areas in: (1) Fall River, MA; (2) Indianapolis, IN; and (3) Tulsa, OK. The three study areas present a variety of circumstances related to population exposure to short-term peak concentrations of SO₂ in ambient air. These study areas range in total population size from approximately 180,000 to 540,000 and reflect different mixtures of SO₂ emissions sources, including electric utilities using fossil fuels, as well as sources such as petroleum refineries and secondary lead smelting (REA, section 3.1). The three study areas – in Massachusetts, Indiana and Oklahoma – are in three different climate regions of the U.S.: the Northeast, Ohio River Valley (Central), and South (Karl and Koss, 1984). The latter two regions comprising the part of the U.S. with generally the greatest prevalence of elevated SO₂ concentrations and large emissions sources (PA, Figure 2-7 and Appendix F).⁶⁴ Accordingly, the three study areas illustrate three different patterns of exposure to SO₂ concentrations in a populated area in the U.S. (REA, section 5.1). While the same air quality scenario is simulated in all three study areas (conditions that just meet the current standard), study-area-specific source and population characteristics contribute to variation in the estimated magnitude of exposure and associated risk across study areas.

As indicated by this case study approach to assessing exposure and risk, the analyses in

⁶⁴ Additionally, continuous 5-minute ambient air monitoring data (i.e., all 5-minute values for each hour) are available in all three study areas (REA, section 3.2).

the REA are intended to provide assessments of an air quality scenario just meeting the current standard for a small, diverse set of study areas and associated exposed at-risk populations that will be informative to the EPA's consideration of potential exposures and risks that may be associated with the air quality conditions occurring under the current SO₂ standard. The REA analyses are not designed to provide a comprehensive national assessment of such conditions (REA, section 2.2). The objective of the REA is not to present an exhaustive analysis of exposure and risk in areas of the U.S. that currently just meet the standard and/or of exposure and risk associated with air quality adjusted to just meet the standard in areas that currently do not meet the standard.⁶⁵ Rather, the purpose is to assess, based on current tools and information, the potential for exposures and risks beyond those indicated by the information available at the time the current standard was established. Accordingly, capturing an appropriate diversity in study areas and air quality conditions (that reflect the current standard scenario) is important to the role of the REA in informing the EPA's conclusions on the public health protection afforded by the current standard (PA, section 3.2.2.2).

A broad variety of spatial and temporal patterns of SO₂ concentrations can exist when ambient air concentrations just meet the current standard. These patterns will vary due to many factors including the types of emissions sources in a study area and several characteristics of those sources, such as magnitude of emissions and facility age, use of various control technologies, patterns of operation, and local factors, as well as local meteorology. Estimates derived by the particular analytical approaches and methodologies used to describe the study area-specific air quality provide an indication of this variability in the spatial and temporal

⁶⁵ Nor is the objective of the REA to provide a comprehensive assessment of current air quality across the U.S.

patterns of SO₂ concentrations associated with air quality conditions just meeting the current standard, while recognizing the associated uncertainty in these concentration estimates.

In this regard, the REA presents results from two different approaches to adjusting air quality. The first approach uses the highest design value across all modeled air quality receptors to adjust the air quality concentrations in each area to just meet the standard (REA, section 3.4). This is done by estimating the amount of SO₂ concentration reduction needed for concentrations at this highest receptor to be adjusted to just meet the current standard. Based on this amount, all other receptors impacted by the highest source(s) are adjusted proportionately. The second approach is included in the REA as a sensitivity analysis in recognition of the potential uncertainty associated with the estimated concentrations across the modeling domain, particularly the very highest concentrations. Accordingly, the second approach uses the air quality receptor having the 99th percentile of the distribution of design values (instead of the receptor having the maximum design value) to estimate the SO₂ concentration reductions needed to adjust the air quality to just meet the standard (REA, section 6.2.2.2).

Consistent with the health effects evidence summarized in section II.B above, the focus of the REA is on short-term (5-minute) exposures of individuals in the population with asthma during times when they are breathing at an elevated rate. Five-minute concentrations in ambient air were estimated for the current standard scenario using a combination of 1-hour concentrations from the EPA's preferred near-field dispersion model, the American Meteorological Society/EPA regulatory model (AERMOD), with adjustment such that they just meet the current standard, and relationships between 1-hour and 5-minute concentrations occurring in the local ambient air monitoring data. Air quality modeling with AERMOD is used to capture the spatial variation in ambient SO₂ concentrations across an urban area, which can be relatively high in

areas affected by large point sources, and which the limited number of monitoring locations in each area is unlikely to capture. This provides 1-hour concentrations at model receptor sites across the modeling domain across the 3-year modeling period (consistent with the 3-year form of the standard). These concentrations were adjusted such that the air quality modeling receptor location with the highest concentrations just met the current standard.⁶⁶ Relationships between 1-hour and 5-minute concentrations at local monitors were then used to estimate 5-minute concentrations associated with the adjusted 1-hour concentrations across the 3-year period at all model receptor locations in each of the three study areas (REA, section 3.5). In this way, available continuous 5-minute ambient air monitoring data (datasets with all twelve 5-minute concentrations in each hour) were used to reflect the fine-scale temporal variation in SO₂ concentrations documented by these data and for which air quality modeling is limited, e.g., by limitations in the time steps of currently available model input data such as for emissions estimates.

The estimated 5-minute concentrations in ambient air across each study area were then used together with the Air Pollutants Exposure (APEX) model, a probabilistic human exposure model that simulates the activity of individuals in the population, including their exertion levels and movement through time and space, to estimate concentrations of 5-minute exposure events

⁶⁶ The air quality adjustments were implemented with a focus on reducing emissions from the source(s) contributing most to the standard exceedances until the areas just met the standard. This approach focuses on the concentrations associated with the primary contributing source(s), identifying the amount by which they need to be adjusted in order for the highest design value across all air quality receptors to just meet the current standard (REA, section 3.4). Based on this amount, all other receptors impacted by the highest source(s) are adjusted accordingly. In recognition of the potential uncertainty associated with this approach, particularly for the highest estimated concentrations, a second approach was also evaluated that bases the adjustments on the air quality receptor having the 99th percentile of the distribution of design values instead of the receptor having the maximum design value (REA, section 6.2.2.1).

of the individuals in indoor, outdoor, and in-vehicle microenvironments. The use of APEX for estimating exposures allows for consideration of factors that affect exposures that are not addressed by consideration of ambient air concentrations alone. These factors include: (1) attenuation in SO₂ concentrations expected to occur in some indoor microenvironments; (2) the influence of human activity patterns on the time series of exposure concentrations; and (3) accounting for human physiology and the occurrence of elevated breathing rates concurrent with SO₂ exposures. These factors are all key to appropriately characterizing health risk for SO₂.

The APEX model has a history of application, evaluation, and progressive model development in estimating human exposure and dose for review of NAAQS for gaseous pollutants (see, e.g., U.S. EPA, 2008b; 2010; 2014d). This general exposure modeling approach was also used in the 2009 REA for the last review of the primary standard for SO_x, although a number of updates have been made to the model and various datasets used with it (2009 REA; REA Planning Document, section 3.4). For example, exposure modeling in the current REA includes reliance on updates to several key inputs of the model, including: (1) a significantly expanded Consolidated Human Activity Database (CHAD), that now has over 55,000 diaries, with over 25,000 school-aged children; (2) updated National Health and Nutrition Examination Survey (NHANES) data (2009-2014), which are the basis for the age- and sex-specific body weight distributions that APEX samples to specify the individuals in the modeled populations; (3) the algorithms used to estimate age- and sex-specific resting metabolic rate, a key input to estimating a simulated individual's activity-specific ventilation (or breathing) rate; and (4) the ventilation rate algorithm itself. Further, the current model uses updated population demographic data based on the most recent Census.

As used in the current assessment, the APEX model probabilistically generates a sample

of hypothetical individuals based on sampling from an actual population database, and simulates each individual's movements through time and space (e.g., indoors at home, inside vehicles) to estimate his or her exposure to a pollutant. Population characteristics are taken into account to represent the demographic profile of the population in each study area. Age and gender demographics for the simulated at-risk population (adults and children with asthma) were drawn from the prevalence estimates provided by the 2011-2015 NHIS.⁶⁷ The APEX model generates each simulated person or profile by probabilistically selecting values for a set of profile variables, including demographic variables, status and physical attributes (e.g., residence with air conditioning, height, weight, body surface area) and ventilation rate.

Based on minute-by-minute activity levels and physiological characteristics of the simulated person, APEX estimates an equivalent ventilation rate (EVR) based on normalizing the simulated individuals' activity-specific ventilation rate to their body surface area; the EVR is used to identify exposure periods during which an individual is at or above a specified ventilation level (REA, section 4.1). The level specified is based on the ventilation rates of subjects in the controlled human exposure studies of exercising people with asthma (ISA, Table 5-2). The APEX simulations performed for this review have focused on exposures to SO₂ emitted into ambient air that occurs in microenvironments⁶⁸ without additional contribution from

⁶⁷ Data for these years were obtained from the NHIS, available at <https://www.cdc.gov/nchs/nhis/data-questionnaires-documentation.htm>.

⁶⁸ Five microenvironments (MEs) are modeled in the REA as representative of a larger number of MEs. The 2009 REA results indicated that the majority of peak SO₂ exposures occurred while individuals were within outdoor MEs (2009 REA, Figure 8-21). Based on that finding and the objective (i.e., understanding how often and where short-term peak SO₂ exposures occur), some MEs that were used in the 2009 REA were aggregated to address exposures of ambient origin that occur within a core group of indoor, outdoor, and vehicle MEs (REA, section 4.2).

indoor SO₂ emissions sources.⁶⁹

The at-risk populations for which exposure and risk are estimated (people with asthma) comprise 8.0 to 8.7% of the populations in the exposure modeling domains for the three study areas (REA, section 5.1). The percent of children with asthma in the simulated populations ranges from 9.7 to 11.2% across the three study areas (REA, section 5.1). Within each study area the percent varies with age, sex and whether family income is above or below the poverty level (REA, section 4.1.2, Appendix E).⁷⁰ This variation is greatest in the Fall River study area, with census block level, age-specific asthma prevalence estimates ranging from 7.9 to 18.6% for girls and from 10.7 to 21.5% for boys (REA, Table 4-1).

As in the last review, the REA for this review uses the APEX model estimates of 5-minute exposure concentrations for simulated individuals with asthma while breathing at elevated rates to characterize health risk in two ways (REA, section 4.5). The first is the percentage of the simulated at-risk populations expected to experience days with 5-minute exposures, while breathing at elevated rates, that are at or above a range of benchmark levels. The second is the percentage of these populations expected to experience days with an occurrence of a doubling or tripling of sRaw. The benchmark concentrations were identified based on consideration of the evidence discussed in section II.B above.

For the benchmark metric, the REA uses benchmark concentrations of 400 ppb, 300 ppb, 200 ppb based on concentrations included in the well-documented controlled human exposure

⁶⁹ Indoor sources of SO₂ are generally minor in comparison to SO₂ from ambient air (ISA, p. 3-6; REA, section 2.1.1 and 2.1.2).

⁷⁰ As described in section 4.1.2 and Appendix E of the REA, asthma prevalence in the exposure modeling domain is estimated based on national prevalence information and study area demographic information related to age, sex and poverty status.

studies summarized in section II.B above, and also 100 ppb in consideration of uncertainties with regard to lower concentrations and population groups with more limited data, as discussed in section II.B above (REA, section 4.5.1). At the upper end of this range, 400 ppb represents the lowest concentration in free-breathing controlled human exposure studies of exercising people with asthma where moderate or greater lung function decrements occurred that were often statistically significant at the group mean level and were frequently accompanied by respiratory symptoms, with some increases in these symptoms also being statistically significant at the group level (ISA, Section 5.2.1.2 and Table 5-2). At 300 ppb, statistically significant increases in lung function decrements (specifically reduced FEV₁) have been documented in analyses of the subset of controlled human exposure study subjects with asthma that are responsive to SO₂ at concentrations below 600 or 1000 ppb (ISA, pp. 5-85 and 5-153 and Table 5-21; Johns et al., 2010). The 200 ppb benchmark concentration represents the lowest level for which individual study subject data are available in terms of the sRaw and FEV₁ from studies that have assessed the SO₂ effect *versus* the effect of exercise in clean air; moderate or greater lung function decrements were documented in some of these study subjects (ISA, Table 5-2 and Figure 5-1; PA, Table 3-1; REA, section 4.6.1). For exposure concentrations below 200 ppb, limited data are available for exposures at 100 ppb that, while not directly comparable to the data at higher concentrations because of differences in methodology and metrics reported,⁷¹ do not indicate that study subjects experienced responses of a magnitude as high as a doubling in sRaw. However, in

⁷¹ As explained in section II.B.3 above, these studies involved exposures via mouthpiece, and only a few of these studies included an exposure to clean air while exercising that would have allowed for determining the effect of SO₂ *versus* that of exercise in causing bronchoconstriction (ISA, section 5.2.1.2; PA, section 3.2.1.3).

consideration of some study subjects with asthma experiencing moderate or greater decrements in lung function at the 200 ppb exposure concentration (approximately 8 to 9% of the study group) and of the paucity or lack of any specific study data for some groups of individuals with asthma, such as primary-school-age children and those with more severe asthma,⁷² a benchmark concentration of 100 ppb (one half the lowest exposure concentration tested in free breathing exposure studies that assessed the SO₂ effect *versus* the effect of exercise in clean air) is also included.

The E-R function for estimating risk of lung function decrements was developed from the individual subject results for sRaw from the controlled exposure studies of exercising freely breathing people with asthma exposed to SO₂ concentrations from 1000 ppb down to as low as 200 ppb (REA, Table 4-11). Beyond the assessment of these studies and their results in past reviews, there has been extensive evaluation of the individual subject results, including a data

⁷² As summarized in section II.B.3 above, recognizing that even the study subjects described as “moderate/severe” group (had well-controlled asthma, were generally able to withhold medication, were not dependent on corticosteroids, and were able to engage in moderate to heavy levels of exercise) would likely be classified as moderate by today’s classification standards (ISA, p. 5-22; Johns et al., 2010; Reddel, 2009), we have considered the evidence with regard to the response of individuals with severe asthma that are not generally represented in the full set of controlled human exposure studies. There is no evidence to indicate such individuals would experience moderate or greater SO₂-related lung function decrements at lower SO₂ exposure concentrations than individuals with moderate asthma. With regard to the severity of response, the limited data that are available indicate a similar magnitude of relative lung function decrements in response to SO₂ as that for individuals with less severe asthma, although the individuals with more severe asthma are indicated to have a larger absolute response and a greater response to exercise prior to SO₂ exposure, indicating uncertainty in the role of exercise *versus* SO₂ and that those individuals “may have more limited reserve to deal with an insult compared with individuals with mild asthma” (ISA, p. 5-22). As noted previously, evidence from controlled human exposure studies are not available for children younger than 12 years old, and the ISA indicates that the information regarding breathing habit and methacholine responsiveness for the subset of this age group that is of primary school age (e.g., 5-12 years) indicates a potential for greater response (ISA, pp. 5-22 to 5.25).

quality review in the last primary SO₂ NAAQS review (Johns and Simmons, 2009), and detailed analysis in two subsequent publications (Johns et al., 2010; Johns and Linn, 2011). The sRaw responses reported in the controlled exposure studies have been summarized in the ISA in terms of percent of study subjects experiencing responses of a magnitude equal to a doubling or tripling or more (e.g., ISA, Table 5-2; Long and Brown, 2018). Across the exposure range from 200 to 1000 ppb, the percentage of exercising study subjects with asthma having at least a doubling of sRaw increases from about 8-9% (at exposures of 200 ppb) up to approximately 50-60% (at exposures of 1000 ppb) (REA, Table 4-11). The E-R function was derived from these data using a probit function (REA, section 4.6.2).

2. Key Limitations and Uncertainties

While the general approach and methodology for the exposure-based assessment in this review is similar to that used in the last review, there are a number of ways in which the current analyses differ and incorporate improvements. For example, in addition to an expansion in the number and type of study areas assessed, input data and modeling approaches have improved in a number of ways, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas. The REA for the current review extends the time period of simulation to a 3-year simulation period, consistent with the form established for the now-current standard. Further, the years simulated reflect more recent emissions and circumstances subsequent to the 2010 decision.

In characterizing uncertainty associated with the risk and exposure estimates in this review, the REA used an approach intended to identify and compare the relative impact that important sources of uncertainty may have (REA, section 6.2). This approach is a qualitative uncertainty characterization approach adapted from the World Health Organization (WHO)

approach for characterizing uncertainty in exposure assessment (WHO, 2008) accompanied by quantitative sensitivity analyses of key aspects of the assessment approach (REA, chapter 6).^{73 74} The REA considers the limitations and uncertainties underlying the analysis inputs and approaches and the extent of their influence on the resultant exposure/risk estimates. Consistent with the WHO (2008) guidance, the overall impact of the uncertainty is scaled by considering the extent or magnitude of the impact of the uncertainty as implied by the relationship between the source of the uncertainty and the exposure/risk output. The REA also evaluated the direction of influence, indicating how the source of uncertainty was judged to affect the exposure and risk estimates (e.g., likely to produce over- or under-estimates).

Several areas of uncertainty are identified as particularly important, with some similarities to those in the last review. Generally, these areas of uncertainty include estimation of the spatial distribution of SO₂ concentrations across each study area under air quality conditions just meeting the current standard, including the fine-scale temporal pattern of 5-minute concentrations. Among other areas, there is also uncertainty with regard to population groups and exposure concentrations for which the health effects evidence base is limited or lacking (PA, section 3.2.2.3).

With regard to the spatial distribution of SO₂ concentrations, there is some uncertainty associated with the ambient air concentration estimates in the air quality scenarios assessed. A

⁷³ The approach used has been applied in REAs for past NAAQS review for nitrogen oxides, carbon monoxide, ozone (U.S. EPA, 2008b; 2010; 2014d), and SO_x (U.S. EPA, 2009).

⁷⁴ The approach used varies from that of WHO (2008) in that the REA approach placed a greater focus on evaluating the direction and the magnitude of the uncertainty (i.e., qualitatively rating how the source of uncertainty, in the presence of alternative information, may affect the estimated exposures and health risk results).

more detailed characterization of contributors to this uncertainty is presented in the REA (REA, section 6.2), with a general summary provided here. Assessment approach-related aspects contributing to this uncertainty include the model estimates of 1-hour concentrations and the approach employed to adjust the air quality surface to concentrations just meeting the current standard,⁷⁵ as well as the estimation of 1-hour ambient air concentrations resulting from emissions sources not explicitly modeled, all of which influence the temporal and spatial pattern of concentrations and associated exposure circumstances represented in the study areas (REA, sections 6.2.1 and 6.2.2). There is also uncertainty in the estimates of 5-minute concentrations in ambient air across the modeling receptors in each study area. The ambient air monitoring dataset available to inform the 5-minute estimates, much expanded in this review over the dataset available in the last review, is used to draw on relationships occurring at one location and over one range of concentrations to estimate the fine-scale temporal pattern in concentrations at the other locations. While this is an important area of uncertainty in the REA results because the ambient air 5-minute concentrations are integral to the 5-minute estimates of exposure, the approach used to represent fine-scale temporal variability in the three study areas is strongly based in the available information and has been evaluated in the REA (REA, Table 6-3; sections 3.5.2 and 3.5.3).

Another important area of uncertainty, particular to interpretation of the lung function

⁷⁵ In study areas in which estimated SO₂ concentrations at a very small number of receptors are substantially higher than those at all other air quality receptors, the two different adjustment approaches investigated in the REA (described in section II.C.1 above) can result in very different concentrations across the area. In areas with this characteristic, the first approach (which involves determining adjustments based on concentrations at the very highest receptor locations) generally results in appreciably lower concentrations than those associated with the second approach at receptor locations beyond the small group with the very highest concentrations in the area. This is discussed in greater detail in the REA, section 6.2.2.2.

risk estimates, concerns estimates derived for exposure concentrations below those represented in the evidence base (REA, Table 6-3). The E-R function on which the risk estimates are based generates non-zero predictions of the percentage of the at-risk population expected to experience a day with at least a doubling of sRaw for all exposures experienced while breathing at an elevated rate. The uncertainty in the response estimates increases substantially with decreasing exposure concentrations below those well represented in the data from the controlled human exposure studies (i.e., below 200 ppb).

Additionally, the assessment focuses on the daily maximum 5-minute exposure during a period of elevated breathing rate, summarizing results in terms of the days on which the magnitude of such exposure exceeds a benchmark or contributes to a doubling or tripling of sRaw. Although there is some uncertainty associated with the potential for additional, uncounted events in the same day, the health effects evidence indicates a lack of a cumulative effect of multiple exposures over several hours or a day (ISA, section 5.2.1.2) and a reduced response to repeated exercising exposure events over an hour (Kehrl et al., 1987). Further, information is somewhat limited with regard to the length of time after recovery from one exposure by which a repeat exposure would elicit a similar effect as that of the initial exposure event (REA, Table 6-3). Another area of uncertainty concerns the potential influence of co-occurring pollutants on the relationship between short-term SO₂ exposures and respiratory effects. For example, there is some limited evidence regarding the potential for an increased response to SO₂ exposures occurring in the presence of other common pollutants such as PM (potentially including particulate sulfur compounds), nitrogen dioxide and ozone, although the studies are limited (e.g., with regard to their relevance to ambient exposures) and/or provide inconsistent results (ISA, pp.

5-23 to 5-26, pp. 5-143 to 5-144; 2008 ISA, section 3.1.4.7).⁷⁶

Another area of uncertainty, which remains from the last review and is important to our consideration of the REA results, concerns the extent to which the quantitative results represent the populations at greatest risk of effects associated with exposures to SO₂ in ambient air. As recognized in section II.B, the controlled human exposure study evidence base does not include studies of children younger than 12 years old and is limited with regard to studies of people with more severe asthma.⁷⁷ The limited evidence that informs our understanding of potential risk to these groups indicates the potential for them to experience greater impacts than other population groups with asthma under similar exposure circumstances or, in the case of people with severe asthma, to have a more limited reserve for addressing this risk (ISA, section 5.2.1.2). Further, we note the lack of information on the factors contributing to increased susceptibility to SO₂-induced bronchoconstriction among some people with asthma compared to others (ISA, pp. 5-19 to 5-21). These data limitations contribute uncertainty to the exposure/risk estimates with regard to the extent to which they represent the populations at greatest risk of SO₂-related respiratory effects.

⁷⁶ For example, “studies of mixtures of particles and sulfur oxides indicate some enhanced effects on lung function parameters, airway responsiveness, and host defense,” however, “some of these studies lack appropriate controls and others involve [sulfur-containing species] that may not be representative of ambient exposures” (ISA, p.5-144). These toxicological studies in laboratory animals, which were newly available in the last review, were discussed in greater detail in the 2008 ISA. That ISA stated that “[r]espiratory responses observed in these experiments were in some cases attributed to the formation of particular sulfur-containing species” yet, “the relevance of these animal toxicological studies has been called into question because concentrations of both PM (1 mg/m³ and higher) and SO₂ (1 ppm and higher) utilized in these studies are much higher than ambient levels” (2008 ISA, p. 3-30).

⁷⁷ We additionally recognize that limitations in the activity pattern information for children younger than five years old precluded their inclusion in the populations of children simulated in the REA (REA, section 4.1.2).

In summary, among the multiple uncertainties and limitations in data and tools that affect the quantitative estimates of exposure and risk and their interpretation in the context of considering the current standard, several are particularly important. These include uncertainties related to estimation of 5-minute concentrations in ambient air; the lack of information from controlled human exposure studies for the lower, more prevalent, concentrations of SO₂ and limited information regarding multiple exposure episodes within a day; the prevalence of different exposure circumstance represented by the three study areas; and characterization of particular subgroups of people with asthma that may be at greater risk.

3. Summary of Exposure and Risk Estimates

The REA provides estimates for two simulated at-risk populations: adults with asthma and school-aged children⁷⁸ with asthma (REA, section 2.2). Focusing on the at-risk population of children with asthma, summarized here are two sets of exposure and risk estimates for the 3-year simulation in each study area: (1) the number (and percent) of simulated persons experiencing exposures at or above the particular benchmark concentrations of interest while breathing at elevated rates; and (2) the number and percent of people estimated to experience at least one SO₂-related lung function decrement in a year and the number and percent of people experiencing multiple lung function decrements associated with SO₂ exposures (detailed results are presented in the REA). Both types of estimates for adults with asthma are lower, generally due to the lesser amount and frequency of time spent outdoors (REA, section 5.2). As described

⁷⁸ The adult population group is comprised of individuals older than 18 years of age and school-aged children are individuals aged 5 to 18 years old. As in other NAAQS reviews, this REA does not estimate exposures and risk for children younger than 5 years old due to the more limited information contributing relatively greater uncertainty in modeling their activity patterns and physiological processes than children between the ages of 5 to 18 (REA, p. 2-8).

in section II.C.1 above, the REA provides results for two different approaches to adjusting air quality. The estimates summarized here are drawn from the results for both approaches.

Table 1 presents the results for the benchmark-based risk metric in terms of the percent of the simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above the different benchmark concentrations while breathing at elevated rates under air quality conditions just meeting the current standard (REA, Tables 6-8 and 6-9). These estimates for the Tulsa study area are much lower than those for the other two areas (Table 1). No individuals of the simulated at-risk population in that study area were estimated to experience exposures at or above 200 ppb and less than 0.5% are estimated to experience an exposure at or above the 100 ppb benchmark.

In the other two study areas (Indianapolis and Fall River), approximately 20% to just over 25% of a study area's simulated children with asthma, on average across the 3-year period, are estimated to experience one or more days per year with a 5-minute exposure at or above 100 ppb while breathing at elevated rates (Table 1). With regard to the 200 ppb benchmark concentration, these two study areas' estimates are as high as 0.7%, on average across the 3-year period, and range up to as high as 2.2% in a single year. Less than 0.1% of either area's children with asthma were estimated to experience multiple days with such an exposure at or above 200 ppb (REA, Tables 6-8 and 6-9). Additionally, in the study area with the highest estimates for 200 ppb (Indianapolis), approximately a quarter of a percent of simulated children with asthma also were estimated to experience a day with a 5-minute exposure at or above 300 ppb across the 3-year period (the percentage for the 400 ppb benchmark was 0.1% or lower). Across all three areas, no children were estimated to experience multiple days with a daily maximum 5-minute exposure (while breathing at an elevated rate) at or above 300 ppb (REA, Table 6-9).

Table 1. Air quality conditions adjusted to just meet the current standard: Percent of simulated populations of children with asthma estimated to experience at least one daily maximum 5-minute exposure per year at or above indicated concentrations while breathing at an elevated rate

5-minute Exposure Concentration (ppb)	Percent (%) of Population of Children (5-18 years) with Asthma Average per year ^A		
	Fall River, MA	Indianapolis, IN	Tulsa, OK
≥ 100	19.4 – 26.7	22.4 – 23.0	0.1 – 0.4
≥ 200	<0.1 ^B – 0.7 ^C	0.6 – 0.7	0
≥ 300	0	0.2 – 0.3 ^D	0
≥ 400		<0.1 – 0.1 ^D	

^A The values presented in each cell are the averages of the results for the three years simulated for the two approaches to air quality adjustment (drawn from Table 6-8 of the REA).

^B <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected exposure in any year.

^C The highest single year result for 200 ppb was for Fall River where the estimate ranged up to 2.2% (for the second air quality adjustment approach in REA, Table 6-8).

^D The highest single year results for 300 and 400 ppb were for Indianapolis where the estimates ranged up to 0.8% and 0.3%, respectively (REA, Table 6-8).

As with the comparison-to-benchmark results, the estimates for risk of lung function decrements in terms of a doubling or more in sRaw are also lower in the Tulsa study area than the other two areas (Table 2; REA, Tables 6-10 and 6-11). Under conditions just meeting the current standard in the Indianapolis and Fall River study areas, as many as 1.3% and 1.1%, respectively, of children with asthma, on average across the 3-year period, were estimated to experience at least one day per year with a SO₂-related doubling in sRaw (Table 2). The corresponding percentage estimates for experiencing two or more such days ranged as high as 0.7%, on average across the 3-year simulation period (REA, Table 6-11). Additionally, as much as 0.2% and 0.3%, in Fall River and Indianapolis, respectively, of the simulated populations of children with asthma, on average across the 3-year period, was estimated to experience a single day with a SO₂-related tripling in sRaw (Table 2).

Table 2. Air quality conditions adjusted to just meet the current standard: Percent of simulated population of children with asthma estimated to experience at least one day per year with a SO₂-related increase in sRaw of 100% or more

Lung function decrement (increase in sRaw)	Percent (%) of Population of Children (5-18 years) with Asthma ^A Average per year		
	Fall River, MA	Indianapolis, IN	Tulsa, OK
≥ 100%	0.9 – 1.1 ^C	1.3 – 1.3	<0.1 ^B - <0.1
≥ 200%	0.1 – 0.2 ^D	0.3 – 0.3 ^D	0
^A The values presented in each cell are the averages of the results for the three years simulated for the two approaches to air quality adjustment (drawn from Table 6-10 of the REA). ^B <0.1 is used to represent nonzero estimates below 0.1%. A value of zero (0) indicates there were no individuals estimated to have the selected decrement in any year. ^C The highest single year result for at least 100% increase in sRaw was for Fall River where the estimate ranged up to 1.9% (for the second air quality adjustment approach in REA, Table 6-10). ^D The highest single year results for at least 200% increase in sRaw were for Indianapolis and Fall River where the estimates ranged up to 0.4% (REA, Table 6-10).			

D. Proposed Conclusions on the Current Standard

In reaching proposed conclusions on the current SO₂ primary standard, the Administrator has taken into account policy-relevant evidence-based and quantitative exposure- and risk-based considerations, as well as advice from the CASAC, and public comment received thus far in the review. Evidence-based considerations draw upon the EPA's assessment and integrated synthesis of the scientific evidence in the ISA of health effects related to SO₂ exposure, with a focus on policy-relevant considerations. Exposure- and risk-based considerations draw upon the EPA's assessment of population exposure and associated risk in the REA, with a focus on effects related to asthma exacerbation in the at-risk population of people with asthma, exposed while breathing at elevated rates, expected to occur under air quality conditions just meeting the current standard.

Building on the discussions of the scientific and technical assessments presented in the ISA and the REA, and summarized in sections II.B and II.C above, section II.D.1 below summarizes evidence- and exposure/risk-based considerations discussed in the PA and

associated conclusions reached in the PA. Section II.D.2 describes advice received from the CASAC. The Administrator's proposed conclusions on the current standard are presented in section II.D.3.

1. Evidence- and Exposure/Risk-Based Considerations in the Policy Assessment

As in previous NAAQS reviews, the role of the PA in this review is to help "bridge the gap" between the Agency's scientific and quantitative assessments presented in the ISA and REA, and the judgments required of the Administrator in determining whether it is appropriate to retain or revise the NAAQS. Evaluations in the PA focus on the policy-relevant aspects of the assessment and integrative synthesis of the currently available health effects evidence in the ISA, the exposure and risk assessments in the REA, and comments and advice of the CASAC, with consideration of public comment on drafts of the ISA, REA, and PA. The PA describes evidence- and exposure/risk-based considerations and presents conclusions for consideration by the Administrator in reaching his proposed decision on the current standard. The main focus of the PA conclusions is consideration of the question: Does the currently available scientific evidence and exposure/risk information, as reflected in the ISA and REA, support or call into question the adequacy of the protection afforded by the current standard?

In considering this question, the PA recognizes as an initial matter that, as is the case in NAAQS reviews in general, the Administrator's conclusions regarding whether the current primary SO₂ standard provides the requisite public health protection under the Act will depend on a variety of factors, including science policy judgments and public health policy judgments. Accordingly, these factors include public health policy judgments concerning the appropriate benchmark concentrations on which to place weight, as well as judgments on the public health significance of the effects that have been observed at the exposures evaluated in the health

effects evidence. Such judgments, in turn, rely on the interpretation of, and decisions as to the weight to place on, different aspects of the results of the REA for the three types of urban exposure circumstances assessed and associated uncertainties. Accordingly, the Administrator's conclusions regarding the current standard will depend in part on judgments regarding aspects of the evidence and exposure/risk estimates, as well as judgments about the public health protection, including an adequate margin of safety, that is requisite under the Clean Air Act.

The PA response to the overarching question above takes into consideration the discussions that address the specific policy-relevant questions for this review, focusing first on consideration of the evidence, as evaluated in the ISA, including that newly available in this review, and the extent to which it alters key conclusions supporting the current standard. The PA also considers the quantitative exposure and risk estimates drawn from the REA, including associated limitations and uncertainties, and the extent to which they may indicate different conclusions from those in the last review regarding the magnitude of risk, as well as level of protection from adverse effects, associated with the current standard. The PA additionally considers the key aspects of the evidence and exposure/risk estimates that were emphasized in establishing the now-current standard, as well as the associated public health policy judgments and judgments about the uncertainties inherent in the scientific evidence and quantitative analyses that are integral to consideration of whether the currently available information supports or calls into question the adequacy of the current primary SO₂ standard.

With regard to the support in the current evidence for SO₂ as the indicator for SO_x, the ISA concludes that of the SO_x, "only SO₂ is present at concentrations in the gas phase that are relevant for chemistry in the atmospheric boundary layer and troposphere, and for human exposures" (ISA, p. 2-18), and also that the available health evidence for SO_x is focused on SO₂

(ISA, p. 5-1). Thus, the PA concludes that the current evidence, including that newly available in this review, continues to support a focus on SO₂ in considering the adequacy of public health protection provided by the primary NAAQS for SO_x.

As described in the PA and summarized in section II.A.1 above, selection of the averaging time for the current standard was based on the need for control of peak SO₂ concentrations that have the potential to contribute to exposures that pose health risks to people with asthma (for which the current evidence is described in section II.B above and considered below). When the standard was set in 2010, the Administrator considered a 5-minute averaging time, concluding that such a standard would result in significant and unnecessary instability in public health protection, and that the requisite protection from 5- to 10-minute exposure events could be provided with a longer, 1-hour averaging time. A 1-hour averaging time was supported by analyses at that time and by CASAC advice. In considering pertinent information newly available in this review, the PA additionally describes analyses of newly available 5-minute and 1-hour concentrations. The PA finds these newly available quantitative analyses to demonstrate the current 1-hour standard to exert control on 5-minute exposures of potential concern that is similar to expectations for such control when the standard was set (PA, section 3.2.4).

With regard to form and level of the standard, as described in the PA and summarized in section II.A.1 above, the 99th percentile daily maximum 1-hour concentration and the level of 75 ppb were chosen for the new standard in 2010 as providing the appropriate degree of public health protection from adverse effects associated with short-term SO₂ exposures. These selections were also consistent with CASAC advice at the time. Newly available in this review are analyses in the REA focused on assessment of exposure and risk for air quality conditions just meeting the current standard in all its elements. In particular, simulation of these conditions

includes use of a 3-year period consistent with the form established for the current standard (PA, section 3.2.2; REA, section 1.3.1). The resultant exposure and risk estimates are presented in the REA and considered in the PA, as summarized below. Based on such considerations, the PA concluded that it is appropriate to consider retaining the current standard, without revision in any of its elements. The CASAC concurred, specifically stating “that all four elements (indicator, averaging time, form, and level) should remain the same” (Cox and Diez Roux, 2018b, p. 3 of letter). As summarized below, the PA considers the information pertaining to the four elements of the standard (indicator, averaging time, level, and form) collectively in evaluating the health protection afforded by the current standard, consistent with the general approach summarized in section II.A above.

In considering the currently available health effects evidence base, augmented in some aspects since the last review, that provides the foundation of our understanding of the health effects of SO₂ in ambient air, the PA gives particular attention to the evidence from controlled human exposure studies that (1) demonstrates that very short exposures (as short as a few minutes) to SO₂, while breathing at an elevated rate, induces bronchoconstriction and associated decrements in lung function, which can be accompanied by symptoms, among individuals with asthma; and, (2) supports the identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA, sections 1.6, 1.7, 1.8, 5.2, 6.6; 2008 ISA; U.S. EPA, 1994). While the evidence base has been augmented since the time of the last review, the newly available evidence does not lead to different conclusions regarding the primary health effects of SO₂ in ambient air or regarding exposure concentrations associated with those effects; nor does it identify different populations at risk of SO₂-related effects (PA, section 3.2.1). In this way, the health effects evidence available in this review is consistent with evidence available in

the last review when the current standard was established (ISA; 2008 ISA; U.S. EPA, 1994).

This strong evidence base continues to demonstrate a causal relationship between short-term SO₂ exposures and respiratory effects, particularly in people with asthma (ISA, p. xlix and section 5.2.1.2). This conclusion is primarily based on evidence from controlled human exposure studies, also available at the time of the last review, that reported lung function decrements and respiratory symptoms in people with asthma exposed to SO₂ for 5 to 10 minutes while breathing at an elevated rate. Support is also provided by the epidemiologic evidence that is coherent with the controlled human exposure studies. As in the last review, the currently available epidemiologic evidence, including that newly available in this review, includes studies reporting positive associations for asthma-related hospital admissions and emergency department visits (of individuals of all ages, including adults and children) with short-term SO₂ exposures (ISA, section 5.2.1.2).⁷⁹

The health effects evidence newly available in this review also does not extend our understanding of the range of 5-minute exposure concentrations that elicit effects in people with asthma exposed while breathing at an elevated rate beyond what was understood in the last review (PA, section 3.2.1.3). As in the last review, 200 ppb remains the lowest concentration tested in exposure studies where study subjects are freely breathing in exposure chambers (ISA, section 5.2.1.2). At that exposure concentration, approximately 8 to 9% of study subjects with asthma, breathing at an elevated rate, experienced moderate or greater lung function decrements following 5- to 10-minute controlled exposures (ISA, Table 5-2). The limited information

⁷⁹ While uncertainties remain related to the potential for confounding by PM or other copollutants and the representation of fine-scale temporal variation in personal exposures, the findings of the epidemiologic studies continue to provide supporting evidence for the conclusion on the causal relationship (ISA, section 5.2.1.2).

available for exposure concentrations below 200 ppb is from mouthpiece exposure studies in which subjects were exposed to a concentration of 100 ppb, with only a few of these studies including an exposure to clean air while exercising that would have allowed for determining the effect of SO₂ *versus* the effect of exercise alone (ISA, section 5.2.1.2; PA, section 3.2.1.3).

While, for these reasons, these data are not amenable to direct quantitative comparisons with the data for higher exposure concentrations, they generally indicate a somewhat lesser response. In considering what may be indicated by the epidemiologic evidence with regard to exposure concentrations eliciting effects, we recognize complications associated with interpretation of epidemiologic studies of SO₂ in ambient air that relate to whether measurements at the study monitors adequately represent the spatiotemporal variability in ambient SO₂ concentrations in the study areas and associated population exposures (ISA, section 5.2.1.9).

In this review, as in the last review, there is uncertainty with regard to exposure levels eliciting effects in some population groups for which data are limited or not available from the controlled human exposure studies, such as individuals with severe asthma and children younger than 12 years old, as well as uncertainty in the extent of effects at exposure levels below those studied (PA, section 3.2.1; ISA, p. 5-22). Collectively, these aspects of the evidence and associated uncertainties contribute to a recognition that for SO₂, as for other pollutants, the available evidence base in this NAAQS review generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

As at the time of the last review, the exposure and risk estimates developed from modeling exposures to SO₂ emitted into ambient air are critically important to consideration of

the potential for exposures and risks of concern under air quality conditions of interest, and consequently they are critically important to judgments on the adequacy of public health protection provided by the current standard. In considering the REA analyses available in this review, the PA notes the various ways in which these analyses differ and improve upon those available in the last review. In addition to an expansion in the number and type of study areas assessed, there are a number of improvements to input data and modeling approaches, including the availability of continuous 5-minute air monitoring data at monitors within the three study areas (PA, section 3.2.2; REA, section 1.3.1). The current REA extends the time period of simulation by including a 3-year simulation period consistent with the form established for the now-current standard (PA, section 3.2.2; REA, section 1.3.1). Further, the years simulated reflect more recent patterns of emissions and associated exposure circumstances subsequent to the 2010 decision (PA, section 3.2.2; REA, section 1.3.1).

As at the time of the last review, people with asthma are the population at risk of respiratory effects related to SO₂ in ambient air. Children with asthma may be particularly at risk (PA section 3.2.1.2; ISA, section 6.5.1.1). While in the U.S. there are more adults with asthma than children with asthma, the REA results, in terms of percent of the simulated at-risk populations, indicate higher exposures and risks for children with asthma as compared to adults. This finding relates to children's greater frequency and duration of outdoor activity (REA, sections 2.1.2, 4.3.3, 4.4, 5.2, and 5.3). In light of these conclusions and findings, we have focused our consideration of the REA results here on the results for children with asthma.

As can be seen by the variation in exposure estimates, the three study areas in the REA represent an array of emissions sources and associated exposure circumstances, including those contributing to relatively higher and relatively lower exposures and associated risk (PA, section

3.2.2; REA, section 5.4).⁸⁰ As recognized in the REA, the analyses there are not intended to provide a comprehensive national assessment. Rather, the analyses for this array of study areas are intended to indicate the magnitude of exposures and risks that may be expected in areas of the U.S. that just meet the current standard but may differ in ways affecting population exposures of interest. In that way, the REA is intended to be informative to the EPA's consideration of potential exposures and risks associated with the current standard and the Administrator's judgments regarding the protection provided by the current standard. For example, the PA considered locations within areas that just meet the current standard where the areas' locations of relatively higher ambient air concentrations coincide with locations of higher population density. In so doing, the PA recognized that consideration of such exposures is particularly important to consideration of the public health protection afforded by the current standard, and particularly to the overarching question concerning the availability of information that calls into question the adequacy of the current standard (PA, sections 3.2.2.2 and 3.2.2.4).

With regard to the REA representation of air quality conditions associated with just meeting the current standard, the PA notes reduced uncertainty (compared to the 2009 REA) in a few aspects of the approach for developing this air quality scenario, while additionally recognizing the uncertainty associated with the application of air quality adjustments to estimate conditions just meeting the current standard (PA, sections 3.2.2.2 and 3.2.2.3; REA, section

⁸⁰ More specifically, the three areas fall into three different geographic regions of the U.S. They range from approximately 180,000 to approximately one half million in total population, and their populations vary in demographic characteristics. Additionally, the types of large sources of SO₂ emissions represented in the three study areas vary with regard to emissions characteristics and include EGUs, petroleum refineries, glass-making facilities, secondary lead smelters (from battery recycling), and chemical manufacturing (REA, section 3.1).

6.2.2). Given the importance of this aspect of the REA to consideration of the level of protection provided by the current standard, the PA considers the results for each study area in terms of a range that reflects variation associated with the two different methodologies for the first air quality adjustment approach (REA, section 6.2.2.2).

In this context, the PA notes that across all three study areas, which provide an array of SO₂ emissions and exposure situations, the percent of children with asthma estimated to experience at least one day with as much as a doubling in sRaw (attributable to SO₂), on average across the 3-year period, ranges from <0.1 % to 1.3%; the highest study area estimate is just under 2% for the highest single year (PA, section 3.2.4; PA, Table 3-4; REA, Table 6-10). Accordingly, results for the three case study areas indicate at least 98.7% or more of the at-risk population of children with asthma to be protected from experiencing a SO₂-related doubling in sRaw, as an average across the 3-year period, and approximately 98% or more protected from as much as a single occurrence in the single highest year. Greater protection (e.g., 99% or more) is indicated for multiple days with a doubling in sRaw and also for single occurrences of as much as a tripling in sRaw (PA, section 3.2.4; REA, Table 6-11).

With regard to exposures compared to benchmark concentrations, the PA notes that less than 1% of children with asthma are estimated to experience, while breathing at an elevated rate, a daily maximum 5-minute exposure per year at or above 200 ppb, on average across the 3-year period, with a maximum for the study area with the highest estimates just over 2% in the highest single year (PA, section 3.2.4; PA, Table 3-3; REA, Table 6-8). Further, the percentage for at least one day with such an exposure at or above 400 ppb is 0.1% or less, as an average across the 3-year period, and 0.3% or less in each of the three years simulated across the three study areas (PA, section 3.2.4; PA, Table 3-3; REA, Table 6-8). No simulated at-risk individuals were

estimated to experience multiple such days (PA, section 3.2.4; REA, Table 6-9).

In considering the public health implications of the REA estimated occurrences of exposures of different magnitudes, the PA takes note of guidance from the ATS (Thurston et al., 2017; ATS, 2000),⁸¹ CASAC advice, and judgments made by the EPA in considering the public health implications of similar effects in previous NAAQS reviews.⁸²

In so doing, the PA finds the REA exposure and risk estimates to indicate that the current standard is likely to provide a high level of protection from SO₂-related health effects to at-risk populations of children and adults with asthma (PA, section 3.2.4). In summarizing these findings, the PA also notes the uncertainties in the REA results (summarized in section II.C.2 above) associated with the limited or lacking evidence from the controlled human exposure studies for some subgroups in these populations such as people with severe asthma and children younger than 12 years old (PA, section 3.2.4).

The PA additionally reflects on the key aspects of the 2010 decision that established the current standard, such as considerations of adversity of SO₂-related effects to health, and also the

⁸¹ As recognized in section II.B.4 above, a recent publication by the ATS provides an updated statement on what constitutes an adverse health effect of air pollution (Thurston et al., 2017). The recent ATS statement, while expanding upon the 2000 ATS statement that was considered in the last review, is generally consistent with it with regard to aspects pertaining to SO₂-related effects. In that review, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO₂ exposures at or above 200 ppb can result in adverse health effects (75 FR 35536, June 22, 2010). In so doing, she also recognized that effects reported for exposures below 400 ppb are less severe than those at and above 400 ppb, which include larger decrements in lung function that are frequently accompanied by respiratory symptoms (75 FR 35547, June 22, 2010).

⁸² Judgments by the EPA across NAAQS reviews for various pollutants have particularly emphasized the protection of at-risk population members from multiple occurrences of exposures or effects of concern and from such effects of greater severity or that have been documented to be accompanied by symptoms (75 FR 35520, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015).

public health implications of associated exposure and risk estimates for simulated at-risk populations. As an initial matter, the 2010 decision recognized that 5 to 10 minutes “exposure to SO₂ concentrations as low as 200 ppb can result in adverse health effects in [people with asthma]” (75 FR 35546, June 22, 2010);⁸³ this judgment was based on consideration of CASAC advice and EPA judgments in prior NAAQS reviews, as well as ATS guidance. Since the last review, the ATS has released an additional statement on adversity of air pollution, which is generally consistent with and supportive of the earlier statement (available at the time of the 2010 decision) and the 2010 judgments. Additionally, the CASAC has provided advice in the context of this SO₂ NAAQS review, which is summarized in section II.D.2 below.

Further, while recognizing the differences between the current REA analyses and the 2009 REA analyses, including the 2009 REA’s lack of an air quality scenario specific to the now-current standard in the last review, as well as uncertainties associated with such analyses, the PA notes a rough consistency of the associated estimates when considering the array of study areas in both reviews (PA, section 3.2.4). Overall, the PA finds the newly available quantitative analyses to comport with the conclusions reached in the last review regarding the control expected to be exerted by the now-current 1-hour standard on 5-minute exposures of concern (PA, section 3.2.4). With regard to the results for the REA in the last review (which were for a single-year simulation), the 2010 decision recognized those results for the area with the highest

⁸³ The decision notice additionally stated that “[t]he Administrator notes that although these decrements in lung function have not been shown to be statistically significant at the group mean level, or to be frequently accompanied by respiratory symptoms, she considers effects associated with exposures as low as 200 ppb to be adverse in light of CASAC advice, similar conclusions in prior NAAQS reviews, and the ATS guidelines described in detail above” and that “[t]herefore, she has concluded it appropriate to place weight on the 200 ppb 5-minute benchmark concentration” (75 FR 35546, June 22, 2010).

estimates and largest population (St. Louis) to indicate that a 1-hour standard of a magnitude between the two levels assessed in the 2009 REA (50 and 100 ppb) might be expected to protect more than 97% of children with asthma (and somewhat less than 100%) from experiencing exposures at or above a 200 ppb benchmark concentration and more than 99% of that population group from experiencing exposures at or above a 400 ppb benchmark (75 FR 35546-47, June 22, 2010; 2009 REA, pp. B-62 and B-63). Single-year results in the current REA for the two study areas with the highest estimates (including the area with the most sizeable population, Indianapolis) indicate protection for the now-current standard of 75 ppb of approximately 98 to 99% of the populations of children with asthma from experiencing exposures at or above a 200 ppb benchmark concentration and 99.7% or more of the study area at-risk populations from exposures at or above 400 ppb (PA, sections 3.2.2.2 and 3.2.4; REA, Table 6-8). These and the similar estimates for a doubling or more in sRaw are of a magnitude roughly consistent with the level of protection that was described in establishing the now-current standard in 2010 (PA, section 3.1.1.2.4).⁸⁴

Additionally, the 2010 decision also took note of the magnitude of the SO₂ concentrations in ambient air in U.S. epidemiologic studies of associations between ambient air concentrations and emergency department visits or hospital admissions, for which the effect estimate remained positive and statistically significant in copollutant models with PM (PA, sections 3.1.1.2.4 and

⁸⁴ For the single-year scenario representing a standard level of 100 ppb in the study area with the highest population exposure and risk (St. Louis), the 2009 REA estimated 2.1-2.9% of children with asthma to experience at least one day with an SO₂-attributable increase in sRaw of at least 100%; the comparable estimates for a level of 50 ppb were 0.4-0.9% (2009 REA, Table 9-8 and Appendix B).

3.2.4).⁸⁵ No additional such studies are available in the current review, as summarized in section II.B.3 above (PA, section 3.2.1.3). Accordingly, in considering the main aspects of the decision in the last review, the PA finds the currently available information to be consistent with that on which the decision establishing the current standard was based (PA, section 3.2.4).

In considering potential public health implications of the current REA exposure and risk estimates for the three case studies, the PA recognizes the importance of these estimates to consideration of whether the currently available information calls into question the adequacy of public health protection afforded by the current standard. In so doing, the PA notes that the REA estimates for conditions associated with just meeting the current standard, are of particular importance to consideration of exposures and risks in areas still existing across the U.S. that have source and population characteristics similar to the study areas assessed, and with ambient concentrations of SO₂ that just meet the current standard today or that will be reduced to do so at some period in the future. In this context, the PA takes note of the more than 24 million people with asthma currently in the U.S., including more than 6 million children, with potentially somewhat more than 100,000 living within 5 km of large⁸⁶ sources of SO₂ emissions (PA, sections 3.2.2.4 and 3.2.4).

The PA additionally takes note of the uncertainties or limitations of the current evidence base with regard to the exposure levels at which effects may be elicited in some population

⁸⁵ In considering these studies and information regarding SO₂ concentrations in the areas studied, as well as associated uncertainties, the Administrator concluded that the level of 75 ppb chosen for the new 1-hour standard provided an adequate margin of safety (PA, section 3.1.1.2.4; 75 FR 35548, June 22, 2010).

⁸⁶ As also summarized in section II.D.1 above, these estimates are drawn from the PA presentation of estimates of the number of children living near SO₂ emissions sources emitting 1,000 tpy based on the 2014 NEI and the 2015 national estimates of asthma prevalence (PA, section 3.2.2.4 and Table 3-5).

groups (e.g., children with asthma and individuals with severe asthma), as well as the severity of the effects in those groups (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5-22 to 5-25). In so doing, the PA recognizes that the controlled human exposure studies, on which the depth of the general understanding of SO₂-related health effects is based, are limited or lacking in providing information with regard to responses in people with more severe asthma or in children younger than 12 years (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5-22 to 5.25). Additional limitations in understanding relate to the potential for effects in some people with asthma exposed to concentrations below 200 ppb, as well as the potential for other air pollutants to affect responses to SO₂ (PA, sections 3.2.1.4 and 3.2.4; ISA, pp. 5-22 to 5-26). In light of these uncertainties, the PA additionally takes note of the REA results for the lowest benchmark concentration (100 ppb) that indicate that in some areas of the U.S. under air quality conditions that just meet the current standard, approximately 20% to just over 25% of children with asthma may experience one or more days per year, on average across a 3-year period, with a 5-minute exposure to concentrations at or above this benchmark while breathing at an elevated rate (PA, section 3.2.4 and Table 3-3; REA, Table 6-8). Based on such consideration of the evidence across the exposure concentrations studied and the exposure/risk information related to the lowest benchmark concentration, the PA finds that the combined consideration of the body of evidence and the quantitative exposure estimates continues to provide support for a standard as protective as the current one (PA, section 3.2.4).

The PA further recognizes that the EPA's conclusions regarding the adequacy of the current standard depend in part on public health policy judgments identified above and judgments by the Administrator about the level of public health protection that is appropriate, allowing for an adequate margin of safety. In so doing, the PA takes note of the long-standing

health effects evidence that documents the effects of SO₂ exposures as short as a few minutes in people with asthma that are exposed while breathing at elevated rates and recognizes that such effects have been documented at the lowest concentration studied in exposure chambers with appropriate clean-air controls (PA, section 3.2.4). The PA additionally notes that it was recognized in the last review that such exposures can result in adverse health effects in people with asthma (75 FR 35546-47, June 22, 2010), and that there are limitations, and associated uncertainty, in the evidence available for the lower exposure concentration of 100 ppb (summarized in section II.B.3 above), as was the case in the last review. The PA further notes the indication of an appreciable reduction in the magnitude of the SO₂-induced response in exercising people with asthma at this lower exposure concentration compared with responses observed for exposures at 200 ppb (PA, sections 3.2.1.3, 3.2.1.4 and 3.2.4). Thus, in focusing on the potential for 5-minute exposures at and above 200 ppb, the PA takes note of the REA results that indicate the current standard may be expected to protect approximately 98% and nearly 99% of populations of children with asthma from experiencing any days with such exposures in the highest year and on average each year in a 3-year period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6-8). The PA additionally notes that the REA estimates indicate the current standard may be expected to protect more than 99% of children from experiencing any days with a 5-minute exposure of 300 ppb or higher, with the estimates for the 400 ppb benchmark indicating protection of at least 99.7% and 99.9% of children with asthma from experiencing any days with a 5-minute exposure of 400 ppb or higher in the highest year and in each year on average for a 3-year period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6-8). In considering these results, the PA notes the lesser severity of effects reported for exposures below 400 ppb than those at and above 400 ppb, which include larger decrements in lung function that

are frequently accompanied by respiratory symptoms, facts given weight in establishing the current standard in 2010 (75 FR 35547, June 22, 2010).⁸⁷ With regard to the potential for children to experience SO₂-related lung function decrements in terms of at least a doubling in sRaw, the PA takes note of the REA results that indicate the current standard may be expected to protect approximately 98.1% and nearly 98.7% from experiencing any days with such decrements, in the highest year of the 3-year period and in each year on average for the period, respectively (PA, sections 3.2.2.4 and 3.2.4; REA, Table 6-10). In light of ATS guidance, CASAC advice and EPA judgments in past NAAQS reviews, the PA finds these results to indicate a high level of protection of at-risk populations from SO₂-related health effects. The PA further notes that this protection is also consistent with the level of protection indicated by the information considered when the standard was set (PA, section 3.2.4). Accordingly, the PA finds that the currently available evidence and quantitative information, including the associated uncertainties, do not call into question the adequacy of protection provided by the current standard and thus support consideration of retaining the current standard, without revision (PA, section 3.2.4).

Overall, the PA recognizes that the newly available health effects evidence, critically assessed in the ISA as part of the full body of evidence, reaffirms conclusions on the respiratory effects recognized for SO₂ in the last review (PA, sections 3.2.1 and 3.2.4). Further, there is a general consistency of the currently available evidence with the evidence that was available in

⁸⁷ In that review, the Administrator judged that the effects reported in exercising people with asthma following 5- to 10-minute SO₂ exposures at or above 200 ppb can result in adverse health effects (75 FR 35536, June 22, 2010). In so doing, she also recognized that effects reported for exposures below 400 ppb are less severe than those at and above 400 ppb, which include larger decrements in lung function that are frequently accompanied by respiratory symptoms (75 FR 35547, June 22, 2010).

the last review, including with regard to key aspects on which the current standard is based (PA, sections 3.2.1 and 3.2.4). The quantitative exposure and risk estimates for conditions just meeting the current standard indicate a similar level of protection, for at-risk populations from respiratory effects considered to be adverse, as that indicated by the information considered in the decision for the 2010 review in establishing the now-current standard (PA, sections 3.2.2 and 3.2.4.). As in the last review, limitations and uncertainties are associated with the available information, as summarized in section 3.2.4 of the PA.

Collectively, the PA finds that the evidence and exposure/risk based considerations provide the basis for its conclusion that consideration should be given to retaining the current standard, without revision (PA, section 3.2.4). Accordingly, and in light of this conclusion that it is appropriate to consider the current standard to be adequate, the PA did not identify any potential alternative standards for consideration in this review (PA, section 3.2.4).

2. CASAC Advice

In the current review of the primary standard for SO_x, the CASAC has provided advice and recommendations in their review of drafts of the IRP, ISA, REA and PA, and of the REA Planning Document.

In their comments on the draft PA, the CASAC concurred with staff's overall preliminary conclusions that "the current scientific literature does not support revision of the primary NAAQS for SO₂," additionally stating the following (Cox and Diez Roux, 2018b, p. 3 of letter).

The CASAC notes that the new scientific information in the current review does not lead to different conclusions from the previous review. Thus, based on review of the current state of the science, the CASAC supports retaining the current standard, and specifically notes that all four elements (indicator, averaging time, form, and level) should remain the same.

The CASAC further stated the following (Cox and Diez Roux, 2018b, p. 3 of letter).

With regard to indicator, SO₂ is the most abundant of the gaseous SO_x species. Because, as the PA states, “the available scientific information regarding health effects was overwhelmingly indexed by SO₂,” it is the most appropriate indicator. The CASAC affirms that the one-hour averaging time will protect against high 5-minute exposures and reduce the number of instances where the 5-minute concentration poses risks to susceptible individuals. The CASAC concurs that the 99th percentile form is preferable to a 98th percentile form to limit the upper end of the distribution of 5-minute concentrations. Furthermore, the CASAC concurs that a three-year averaging time for the form is appropriate.

The choice of level is driven by scientific evidence from the controlled human exposure studies used in the previous NAAQS review, which show a causal effect of SO₂ exposure on asthma exacerbations. Specifically, controlled five-minute average exposures as low as 200 ppb lead to adverse health effects. Although there is no definitive experimental evidence below 200 ppb, the monotonic dose-response suggests that susceptible individuals could be affected below 200 ppb. Furthermore, short-term epidemiology studies provide supporting evidence even though these studies cannot rule out the effects of co-exposures and are limited by the available monitoring sites, which do not adequately capture population exposures to SO₂. Thus, the CASAC concludes that the 75 ppb average level, based on the three-year average of 99th percentile daily maximum one-hour concentrations, is protective and that levels above 75 ppb do not provide the same level of protection.

The comments from the CASAC also took note of the uncertainties that remain in this review. In so doing, it stated that the “CASAC notes that there are many susceptible subpopulations that have not been studied and which could plausibly be more affected by SO₂ exposures than adults with mild to moderate asthma,” providing as examples people with severe asthma and obese children with asthma, and citing physiologic and clinical understanding (Cox and Diez Roux, 2018b, p. 3 of letter). The CASAC stated that “[i]t is plausible that the current 75 ppb level does not provide an adequate margin of safety in these groups[, h]owever because there is considerable uncertainty in quantifying the sizes of these higher risk subpopulations and the effect of SO₂ on them, the CASAC does not recommend reconsideration of the level at this time” (Cox and Diez Roux, 2018b, p. 3 of letter).

The CASAC comments additionally state that the draft PA “clearly identifies most of the

key uncertainties, including uncertainties in dose-response” and that “[t]here are also some additional uncertainties that should be mentioned” (Cox and Diez Roux, 2018b, pp. 6-7 of Consensus Responses to Charge Questions). These are in a variety of areas including risk for various population groups, personal exposures to SO₂, and estimating short-term ambient air concentrations.⁸⁸ The CASAC suggested research and data gathering in these and other areas that would inform the next SO₂ primary standard review (Cox and Diez Roux, 2018b, p. 6 of the Consensus Responses to Charge Questions).

3. Administrator’s Proposed Conclusions on the Current Standard

Based on the large body of evidence concerning the health effects and potential public health impacts of exposure to SO_x in ambient air, and taking into consideration the attendant uncertainties and limitations of the evidence, the Administrator proposes to conclude that the current primary SO₂ standard provides the requisite protection of public health, including an adequate margin of safety, and should therefore be retained, without revision. In reaching these proposed conclusions, the Administrator has carefully considered the assessment of the available health effects evidence and conclusions contained in the ISA; the quantitative analyses in the REA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC (summarized in section II.D.2 above); and public comments received to date in this review.⁸⁹

⁸⁸ These and other comments from the CASAC on the draft PA and REA were considered in preparing the final PA and REA (USEPA, 2018a,b).

⁸⁹ For example, of the limited public comments received in the docket for this review to date that have addressed adequacy of the current primary standard for SO_x, two commenters, one a state agency and one an industry organization, support retaining the current standard without revision. Two other industry organizations suggest that consideration be given to an increased level for the 1-hour standard. One of these suggested a doubling in the level, while the sole commenting environmental organization suggested reducing the level by half.

In the discussion below, the Administrator considers first the evidence base on health effects associated with short-term exposure to SO₂, including the controlled human exposure studies that document respiratory effects in people with asthma exposed for as short as a few minutes while breathing at elevated rates and the relative lack of such information for some subgroups of this population, including young children and people with severe asthma. He additionally notes the available epidemiologic evidence that documents associations between short-term concentrations of SO₂ in ambient air and asthma-related health outcomes, particularly in children. Further, the Administrator considers the estimates of SO₂ exposures and risk in multiple study areas under air quality conditions just meeting the current standard (summarized in sections II.C and II.D.1 above), and the public health implications of those results. The Administrator additionally considers uncertainties in the evidence and the exposure/risk information, as a part of public health policy judgments essential to decisions regarding the adequacy of the protection provided by the standard, similar to the judgements made in establishing the current standard. He draws on the PA considerations, and PA conclusions in the current review, with which the CASAC has concurred, taking note of key aspects of the rationale presented for those conclusions. Further, the Administrator considers the advice of the CASAC, including particularly its overall agreement with the PA conclusion that the current evidence and quantitative exposure and risk estimates provide support for retaining the current standard and the CASAC's recommendation to retain all elements of the standard without revision (Cox and Diez Roux, 2018b).

With regard to the evidence base for SO₂, the Administrator first recognizes the long-standing evidence that has established the key aspects of the harmful effects of very short SO₂ exposures on people with asthma that are relevant to this review as they were relevant in 2010

when the current short-term standard was established. This evidence, drawn largely from the controlled human exposure studies, demonstrates that very short exposures (for as short as a few minutes) to less than 1000 ppb SO₂, while breathing at an elevated rate (such as while exercising), induces bronchoconstriction and related respiratory effects in people with asthma and supports identification of people with asthma as the population at risk from short-term peak concentrations in ambient air (ISA; 2008 ISA; U.S. EPA, 1994).⁹⁰ The evidence base additionally includes epidemiologic studies that provide support for the conclusion of a causal relationship between short-term SO₂ exposures and respiratory effects for which the controlled human exposure studies are the primary evidence. The epidemiologic studies report positive associations of short-term (i.e., hourly or daily) concentrations of SO₂ in ambient air with asthma-related health outcomes, including hospital admissions and emergency department visits. In considering these epidemiologic studies in the context of the larger evidence base, the ISA recognizes that while these studies analyze hourly or daily metrics, there is the potential for shorter-term concentrations within the study areas to be playing a role in such associations. The ISA also notes associated uncertainties related to potential confounding from co-occurring pollutants such as PM, a chemical mixture including some components for which SO₂ is a precursor, and also related to exposure estimates and the ability of fixed-site monitors to adequately represent variations in personal exposure, particularly with regard to peak exposures, as summarized in section II.B.3 above (ISA, p. 5-37; PA, section 3.2.1.4).⁹¹

With regard to the health effects evidence newly available in this review, the

⁹⁰ For people without asthma, such effects have only been observed in studies of exposure concentrations at or above 1000 ppb (ISA, section 5.2.1.7).

⁹¹ Sulfur dioxide is a precursor to sulfate, which commonly occurs in particulate form (ISA, section 2.3; U.S. EPA, 2009, section 3.3.2 and Table 3-2).

Administrator takes note of the PA finding that, while the health effects evidence, as assessed in the ISA, has been augmented with additional studies since the time of the last review, including more than 200 new health studies, the newly available evidence does not lead to different conclusions regarding the primary health effects of SO₂ in ambient air or regarding exposure concentrations associated with those effects. Nor does it identify different or additional populations at risk of SO₂-related effects. Thus, the Administrator recognizes that the health effects evidence available in this review is consistent with evidence available in the last review when the current standard was established and that this strong evidence base continues to demonstrate a causal relationship between relevant short-term exposures to SO₂ and respiratory effects, particularly with regard to effects related to asthma exacerbation in people with asthma. He also recognizes that the ISA conclusion on the respiratory effects caused by short-term exposures is based primarily on evidence from controlled human exposure studies, available at the time of the last review, that reported moderate or greater lung function decrements and respiratory symptoms in people with asthma exposed to SO₂ for 5 to 10 minutes while breathing at an elevated rate (ISA, section 5.2.1.9), and that the current 1-hour standard was established to provide protection from effects such as these (75 FR 35520, June 22, 2010). The Administrator further notes the control of peak 5-minute exposures that is provided by the current 1-hour standard, as indicated by the exposure analysis in the REA and air quality analyses in the PA (PA, chapter 2 and Appendix B).

With regard to exposure concentrations of interest in this review, the Administrator takes particular note of the evidence from controlled human exposure studies that demonstrate the occurrence of lung function decrements, at times accompanied by respiratory symptoms, in subjects with asthma exposed for very short periods of time while breathing at elevated rates,

focusing primarily on such study findings for which exposure concentration-specific data are available to the EPA for individual subjects (ISA, Table 5-2 and Figure 5-1, summarized in Table 3-1 of the PA).⁹² These data demonstrate such effects related to asthma exacerbation in sensitive people with asthma exposed to SO₂ concentrations as low as 200 ppb. These data include limited evidence of respiratory symptoms accompanying the lung function effects at this exposure level (ISA, Table 5-2). The Administrator recognizes that both the percent of individuals experiencing lung function decrements and the severity of the decrements, as well as the frequency with which they are accompanied by symptoms, increase with increasing SO₂ concentrations across the range of exposure levels studied (ISA, Table 5-2; PA, section 3.2.1.3). For example, approximately 10% of study subjects experienced moderate or greater lung function decrements at 200 ppb, while at 300-400 ppb, as many as approximately 30% of subjects in some studies experienced such decrements. Further, at concentrations at or above 400 ppb, the moderate or greater decrements in lung function were frequently accompanied by respiratory symptoms, such as cough, wheeze, chest tightness, or shortness of breath, with some of these findings reaching statistical significance at the study group level (ISA, Table 5-2 and section 5.2.1).

In considering the potential public health significance of effects associated with SO₂ exposures, the Administrator further recognizes the greater significance accorded both to larger lung function decrements, which are more frequently documented at exposures above 200 ppb, and the potential for greater impacts of SO₂-induced decrements in people with more severe

⁹² The availability of individual subject data allowed for the comparison of results in consistent manner across studies (ISA, Table 5-2; Long and Brown, 2018).

asthma, as recognized in the ISA and by the CASAC (as summarized in section II.D.2 above).⁹³

For example, he notes that the ATS indicated it to be appropriate to consider small lung function changes as adverse when they occur in individuals with pre-existing compromised function, “such as resulting from asthma, even without accompanying respiratory symptoms” (Thurston et al., 2017). Thus, with regard to the health effects evidence for SO₂, the Administrator recognizes that health effects resulting from exposures at and above 400 ppb are appreciably more severe than those elicited by exposure to SO₂ concentrations as low as 200 ppb (and lower), and that health impacts of short-term SO₂ exposures (including those occurring at concentrations below 400 ppb) have the potential to be more significant in the subgroup of people with asthma that have more severe disease and for which the study data are more limited.

As at the time of the last review, the Administrator considers the health effects evidence in the context of the exposure and risk modeling, including key limitations and uncertainties, as summarized in the PA and section II.C.1 above (described in detail in the REA). In so doing, he recognizes such a context to be critical for SO₂, for which health effects in people with asthma are linked to exposures during periods of elevated breathing rates, such as while exercising. Thus, population exposure modeling that takes activity levels into account is integral to consideration of population exposures compared to benchmark concentrations and of population risk of lung function decrements.

In considering the exposure and risk estimates, the Administrator recognizes that unlike

⁹³ The ISA notes that while the extremely limited evidence for adults with moderate to severe asthma indicates such groups may have similar relative lung function decrements in response to SO₂ as adults with less severe asthma, individuals with severe asthma may have greater absolute decrements that may relate to the role of exercise (ISA, p. 1-17 and 5-22). The ISA concluded that individuals with severe asthma may have “less reserve capacity to deal with an insult compared with individuals with mild asthma” (ISA, p. 1-17 and 5-22).

the REA available in the last review, which analyzed single-year air quality scenarios for potential standard levels bracketing the now current level, the current REA assesses an air quality scenario for three years of air quality conditions that just meet the current standard, including its 3-year form. The other ways in which the current REA analyses are improved and expanded from those in the REA for the last review relate to improvements that have been made to models, model inputs and underlying databases. These improvements include the database, vastly expanded since the last review, of ambient air monitoring data for 5-minute concentrations. These data are available as a result of the monitoring data reporting requirement established in the last review to inform subsequent primary NAAQS reviews for SO_x and the associated assessments of the protection provided from elevated short-term (5- to 10-minute exposure) SO₂ concentrations for people with asthma breathing at elevated rates (75 FR 35567-68, June 22, 2010). The current REA is additionally expanded from the prior one with regard to the number of study areas in that it now includes three urban areas, each with populations of more than 100,000 people, as contrasted to the single such area in the 2009 REA.

In considering the REA results for the benchmark comparisons for the three years analyzed in each of the three study areas, the Administrator notes the estimates of as many as 0.7% of children with asthma to experience a single day per year (on average across the 3-year period) with a 5-minute exposure at or above 200 ppb in a single year, while breathing at elevated rates, and as many as 2.2% in a single year. He additionally takes note of the REA findings that also estimate somewhat less than 0.1% of children with asthma to experience multiple days with such exposures in any one year. In turning to consideration of the REA estimates of lung function risk, the Administrator notes that as many as 1.9% of children with asthma are estimated to experience a day in a single year with an SO₂-related doubling of sRaw,

and as many as 1.3% per year on average across three years. He further takes note that as many as 1% of children with asthma may be estimated to experience multiple days in a single year (0.7% on average across multiple years) with a lung function decrement of such a magnitude, and as many as 0.3% (on average across multiple years) may be estimated to experience a day with at least a tripling in sRaw (as summarized in section II.C.3 above).

In considering the level of protection indicated by these estimates of exposure and risk under air quality conditions that just meet the current standard, the Administrator additionally recognizes the limitations in the available evidence base that contribute to uncertainties with regard to the risk estimates for lung function decrements in young children with asthma and in individuals of any age with severe asthma. While health effects study data are limited or lacking for these population groups, the ISA indicates a potential for these groups to experience somewhat greater health impacts than the populations studied (as summarized in section II.B above). In light of these limitations of the evidence and the potential articulated in the ISA for the risk to be greater for these groups for which the evidence is limited or lacking, the Administrator notes that the CAA requirement that primary standards provide an adequate margin of safety, as summarized in section I.A above, is intended to address uncertainties associated with inconclusive scientific and technical information, as well as to provide a reasonable degree of protection against hazards that research has not yet identified.

The Administrator additionally notes the PA consideration of the sizeable number of at-risk individuals living in locations near large SO₂ emissions sources that may contribute to increased SO₂ concentrations in ambient air. The information concerning population exposure characteristics such as the co-occurrence of elevated ambient air concentrations with areas of relatively higher population density is not available for all of these locations. Consideration of

the population sizes in these areas and the potential for similarity of exposure characteristics in some of these areas to the study areas assessed in the REA (as summarized in section II.D.1 above) confirms the public health relevance of the REA results to this review of the current standard.

In considering the adequacy of the protection provided by the current standard, the Administrator notes the findings of the REA in light of considerations recognized above regarding the significance associated with different exposure benchmark concentrations and severity of lung function decrements, as well as the estimated frequency of occurrence of such concentrations and decrements under air quality conditions just meeting the current standard. Given the clear concentration-response relationship documented in the evidence for the key effects in people with asthma across the range of exposure concentrations studied, higher SO₂ concentrations would be expected to contribute to greater severity and frequency in occurrence of responses in at-risk groups. Other considerations summarized above, include the strong evidence for lung function decrements in people with asthma exposed for just a few minutes while breathing at elevated rates (e.g., while exercising) to SO₂ concentrations as low as 200 ppb, the public health implications of such exposures, and related considerations raised by the ATS in its statement on adverse effects of air pollution. Further, advice from the CASAC included its conclusion that the current evidence and exposure/risk information supports retaining the current standard and its associated caution as to uncertainty in the adequacy of the margin of safety provided by the current standard for less well studied yet potentially susceptible

population groups.⁹⁴ Based on all of these considerations, the Administrator gives weight to the PA findings, summarized in section II.D.1 above, that the current body of evidence, in combination with the exposure/risk information, does not support a primary standard that is less protective than the current standard. Thus, he proposes to conclude that a less stringent standard would not provide the requisite protection of public health, including an adequate margin of safety.

Turning to consideration of the adequacy of protection provided by the current standard from effects associated with lower exposures, including those at or below 200 ppb, the Administrator considers the public health significance of the REA estimates for such effects, and of single (*versus* multiple) occurrences of exposures at or above the lower benchmark concentrations and associated lung function decrements, and the nature and magnitude of the various uncertainties that are inherent in the underlying scientific evidence and REA analyses. In so doing, the Administrator recognizes that our understanding of the relationships between the presence of a pollutant in ambient air and associated health effects is based on a broad body of information encompassing not only more established aspects of the evidence, but also aspects with which there may be substantial uncertainty. In the case of the primary SO₂ standard review, he considers the increased uncertainty recognized in the PA with regard to characterization of the risk of lung function decrements (including their magnitude and prevalence, and the associated health significance) at exposure levels below those represented in the controlled human exposure

⁹⁴ In conveying this caution related to such population groups, the CASAC additionally recognized there to be “considerable uncertainty” and concluded that “the CASAC does not recommend reconsideration of the level in order to provide a greater margin of safety” (Cox and Diez Roux, 2018, Consensus Responses, p. 5).

studies and in populations potentially at risk⁹⁵ but for which the evidence base is limited or lacking (PA, section 3.2.2.3; REA, section 5.3). He additionally considers the uncertainties recognized in the PA, and summarized in section II.B and II.D.1 above, regarding exposure measurement error and copollutant confounding in the epidemiologic evidence. In so doing, the Administrator recognizes that collectively, these aspects of the evidence and associated uncertainties support an acknowledgment that for SO₂, as for other pollutants, the available health effects evidence generally reflects a continuum, consisting of levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain.

In considering the point at which health effects associated with lower levels of SO₂ exposure become important from a public health perspective, the Administrator takes note of the PA consideration of the CASAC advice and EPA judgments in establishing the current standard in 2010, as well as the currently available information and commonly accepted guidelines or criteria within the public health community, including the ATS, an organization of respiratory disease specialists,⁹⁶ for interpreting public health significance of moderate or greater lung function decrements, particularly when accompanied by respiratory symptoms, and their occurrence in a portion of the at-risk populations. In so doing, the Administrator additionally notes that the most recent ATS statement on adversity of air pollution is generally consistent with its prior statement that was referenced when the current standard was set (PA, section 3.2.1.5.). He also takes note of EPA judgments in prior NAAQS decisions for SO_x and other

⁹⁵ Such populations include those for which the CASAC described there to be “considerable uncertainty” (Cox and Diez Roux, 2018, Consensus Responses, p. 5).

⁹⁶ With regard to commonly accepted guidelines or criteria within the public health community, the PA considered statements issued by the ATS (as summarized in section II.D.1 above).

pollutants that, consistent with these statements, have particularly emphasized the protection of at-risk population members from multiple occurrences of exposures or effects of concern and from such effects of greater severity or that have been documented to be accompanied by symptoms (75 FR 35520, June 22, 2010; 76 FR 54308, August 31, 2011; 80 FR 65292, October 26, 2015). Together these factors inform the Administrator's consideration in this review of public health implications of the exposure and risk estimates for air quality conditions just meeting the current primary SO₂ standard.

Thus, in considering the evidence and quantitative exposure and risk estimates available in this review with regard to the adequacy of public health protection provided by the current primary standard from respiratory effects associated with the lowest SO₂ exposure concentrations represented in the health effects evidence, the Administrator recognizes that, as noted in section II.A above, the final decision on such judgments is largely a public health policy judgment that draws upon scientific information and analyses about health effects and risks, as well as judgments about how to consider the range and magnitude of uncertainties that are inherent in the information and analyses. These judgments are informed by the recognition, noted just above, that the available health effects evidence generally reflects a continuum, consisting of ambient levels at which scientists generally agree that health effects are likely to occur, through lower levels at which the likelihood and magnitude of the response become increasingly uncertain. Accordingly, the Administrator's final decision requires judgments based on an interpretation of the evidence and other information that neither overstates nor understates the strength and limitations of the evidence and information nor the appropriate inferences to be drawn. As described in section I.A above, the Act does not require that primary standards be set at a zero-risk level; the NAAQS must be sufficient but not more stringent than necessary to

protect public health, including the health of sensitive groups, with an adequate margin of safety.

In this light, the Administrator takes note of PA considerations regarding the REA results and the associated uncertainties (summarized in section II.C above), as well as the nature and magnitude of the uncertainties inherent in the scientific evidence upon which the REA is based. The Administrator finds such considerations collectively to be important to judgments such as the extent to which the exposure and risk estimates for air quality conditions that just meet the current standard in the three study areas indicate exposures and risks that are important from a public health perspective.⁹⁷ In turning first to the REA estimates of the percent of children with asthma estimated to experience a day with a 5-minute SO₂ exposure, while breathing at elevated rates, above benchmark concentrations, the Administrator notes the very small percentage (no more than 0.3% in the highest year) of children with asthma estimated to experience a single day per year at/above the benchmark concentration of 400 ppb, an exposure level frequently associated with respiratory symptoms in controlled human exposure studies. In particular, he takes note of the fact that the REA results do not estimate any children in any of the three study areas to experience more than one such exposure in a year. The Administrator considers these results to represent a very high level of protection (at least 99.7% protected from a single occurrence in the highest year and 100% protected from multiple occurrences) from the risk of respiratory effects that have been observed to occur in as many as approximately 25% of controlled human exposure study subjects with asthma exposed to 400 ppb while breathing at elevated rates, and that have frequently been accompanied by respiratory symptoms. The Administrator additionally notes the small percentage (no more than approximately 2% in the

⁹⁷ Such judgments are among those important to decisions on the adequacy of the margin of safety allowed by the current standard.

highest year) of children with asthma estimated to experience a single day with a 5-minute exposure at or above the lower exposure concentration of 200 ppb, and that less than 0.1% of that population group is estimated to experience more than a single such day in the highest year. In so doing, he recognizes, as did the Administrator in the last review, that effects resulting from this lower exposure concentration are appreciably less severe (e.g., in terms of prevalence of study subjects experiencing a tripling or more in sRaw as well as a 20% reduction in FEV₁) than those elicited by exposures at or above 400 ppb, and that they are less frequently accompanied by respiratory symptoms (ISA, Table 5-2 and Figure 5-1; PA, Table 3-1 and section 3.2.1.3).

The Administrator additionally considers the PA findings regarding the REA estimates of lung function risk in terms of lung function decrements as assessed using doubling and tripling of sRaw. The Administrator finds the REA estimates to indicate a high level of protection for children with asthma against the risk of lung function decrements, and particularly against the larger decrements (e.g., tripling in sRaw) and against multiple occurrences. The REA results for air quality conditions that just meet the current standard indicate, based on average estimates across the 3-year period, protection of more than 99.7% of children with asthma from experiencing a day per year with a SO₂-related tripling of sRaw and at least 99.8% from experiencing multiple such days per year. The results further indicate 99% or more of children with asthma to be protected from multiple days with a SO₂-related doubling of sRaw.

Taking the REA estimates of exposure and risk together, while recognizing the uncertainties associated with such estimates for the scenarios of air quality developed to represent conditions just meeting the current standard, the Administrator considers the current standard to provide a high degree of protection to at-risk populations from SO₂ exposures associated with health effects of public health concern, as indicated by the extremely low

estimates of occurrences of exposures at or above 400 ppb (and at or above 300 ppb). He further considers the current standard to additionally provide a slightly lower, but still high, degree of protection for the appreciably less severe effects associated with lower exposures (i.e., at and below 200 ppb), for which public health implications are less clear. In considering the adequacy of protection provided by the current standard from these lower exposure concentrations, the Administrator additionally takes note of the array of limitations in the evidence summarized above with regard to characterizing the potential response of at-risk individuals to exposures below 200 ppb, which the PA indicates to be much reduced. He also notes the limitations in the evidence for population groups potentially at risk but for which the evidence of risk is limited (PA, section 3.2.2.3; REA, section 5.3). Based on these and all of the above considerations, the Administrator proposes to conclude that a more stringent standard is not needed to provide requisite protection and that the current standard provides the requisite protection of public health under the Act.

With regard to key aspects of the specific elements of the standard, the Administrator recognizes first the support in the current evidence base for SO₂ as the indicator for SO_x. In so doing, he notes the ISA conclusion that SO₂ is the most abundant of the SO_x in the atmosphere and the one most clearly linked to human health effects, as described in the PA and summarized in sections II.B.1 and II.D.1 above. He additionally recognizes the control exerted by the 1-hour averaging time on 5-minute ambient air concentrations of SO₂ and the associated exposures of particular importance for SO₂-related health effects. Lastly, with regard to form and level of the standard, the Administrator takes note of the REA results as discussed above and the level of protection that they indicate the elements of the current standard to provide. The Administrator additionally takes note of the CASAC support for retaining the current standard and the

CASAC's specific recommendation that all four elements should remain the same. Beyond his recognition of this support in the available information and in CASAC advice for the elements of the current standard, the Administrator has considered the elements collectively in evaluating the health protection afforded by the current standard, as described above.

Thus, based on consideration of the evidence and exposure/risk information available in this review with its attendant uncertainties and limitations and information that might inform public health policy judgments, as well as advice from the CASAC, including their concurrence with the PA conclusions that the current evidence does not support revision of the primary SO₂ standard, the Administrator further proposes to conclude that it is appropriate to retain the current standard without revision. The Administrator bases these proposed conclusions on consideration of the health effects evidence, including consideration of this evidence in the context of the quantitative exposure and risk analyses, recognizing the uncertainties associated with both. Inherent in the Administrator's proposed conclusions are public health policy judgments, including those regarding the public health significance of the SO₂-related effects estimated to occur in small portions of the at-risk populations under air quality conditions adjusted to just meet the current standard. In reaching his proposed conclusion on the adequacy of public health protection afforded by the existing primary standard, the Administrator recognizes that the Act requires primary standards to be requisite to protect public health with an adequate margin of safety, and neither more nor less stringent than necessary for this purpose (see generally, *Whitman v. American Trucking Associations*, 531 U.S. 457, 465-472, 475-76 [2001]). The Administrator also recognizes that the Act does not require that primary standards be set at a zero-risk level or to protect the most sensitive individual, but rather at a level that avoids unacceptable risks to public health, even if the risk is not precisely identified as to nature

or degree. The Administrator finds the current standard to provide such a level of public health protection. Thus, the Administrator proposes to conclude that the current primary SO₂ standard provides an adequate margin of safety against adverse effects associated with short-term exposures to SO_x in ambient air. For these reasons, and all of the reasons discussed above, and recognizing the CASAC conclusion that the current evidence and REA results provide support for retaining the current standard, the Administrator proposes to conclude that the current primary SO₂ standard is requisite to protect public health with an adequate margin of safety from effects of SO_x in ambient air and should be retained, without revision. The Administrator solicits comment on this proposed conclusion.

Having reached the proposed decision described here based on interpretation of the health effects evidence, as assessed in the ISA, and the quantitative analyses in the REA; the evaluation of policy-relevant aspects of the evidence and quantitative analyses in the PA; the advice and recommendations from the CASAC; public comments received to date in this review; and the public health policy judgments described above, the Administrator recognizes that other interpretations, assessments and judgments might be possible. Therefore, the Administrator solicits comment on the array of issues associated with review of this standard, including public health and science policy judgments inherent in the proposed decision, as described above. The EPA also solicits comment on the four basic elements of the current NAAQS (indicator, averaging time, level, and form), including whether there are appropriate alternative approaches for the averaging time or statistical form that provide comparable public health protection, and the rationale upon which such views are based.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at

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<http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

The Office of Management and Budget (OMB) determined that this action is a significant regulatory action and it was submitted to OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. Because this action does not propose to change the existing primary NAAQS for SO_x, it does not impose costs or benefits relative to the baseline of continuing with the current NAAQS in effect. EPA has thus not prepared a Regulatory Impact Analysis for this action.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is not expected to be an EO 13771 regulatory action. There are no quantified cost estimates for this proposed action because EPA is proposing to retain the current standard.

C. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. There are no information collection requirements directly associated with a decision to retain a NAAQS without any revision under section 109 of the CAA and this action proposes to retain the current primary SO₂ NAAQS without any revisions.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. Rather, this action proposes to retain, without revision, existing national standards for allowable concentrations of SO₂ in ambient air as required by section 109 of the CAA. See also *American Trucking Associations v. EPA*, 175 F.3d 1027, 1044-45 (D.C. Cir. 1999) (NAAQS do

not have significant impacts upon small entities because NAAQS themselves impose no regulations upon small entities), rev'd in part on other grounds, *Whitman v. American Trucking Associations*, 531 U.S. 457 (2001).

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. It does not have a substantial direct effect on one or more Indian Tribes. This action does not change existing regulations; it proposes to retain the current primary NAAQS for SO₂, without revision. The primary NAAQS protects public health, including the health of at-risk or sensitive groups, with an adequate margin of safety. Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866. The health effects evidence and risk assessment information for this action, which focuses on children with asthma as a key at-risk population, is summarized in sections II.B and II.C above and described in the ISA and PA, copies of which are in the public docket for this action.

I. Executive Order 13211: Actions that Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The purpose of this document is to propose to retain the current primary SO₂ NAAQS. This proposal does not change existing requirements. Thus, the EPA concludes that this proposal does not constitute a significant energy action as defined in Executive Order 13211.

J. National Technology Transfer and Advancement Act

This action does not involve technical standards.

K. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority, low-income populations and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). The documentation related to this is contained in section II above. The action proposed in this notice is to retain without revision the existing primary NAAQS for SO₂ based on the Administrator's conclusion that the existing standard protects public health, including the health of sensitive groups, with an adequate margin of safety. As discussed in section II, the EPA expressly considered the available information regarding health effects among at-risk populations in reaching the proposed decision that the existing standard is requisite.

L. Determination Under Section 307(d)

Section 307(d)(1)(V) of the CAA provides that the provisions of section 307(d) apply to "such other actions as the Administrator may determine." Pursuant to section 307(d)(1)(V), the Administrator determines that this action is subject to the provisions of section 307(d).

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List of Subjects in 40 CFR Part 50

Environmental protection, Air pollution control, Carbon monoxide, Lead, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated:

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Administrator.